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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Vol. 12, No. 1, January 28, 1983

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HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

The **GUIDE** *is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.*

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

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NOTICE

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WITHDRAWAL OF NIA SPECIAL INITIATIVE GRANTS ON AGING

NATIONAL INSTITUTE ON AGING

The National Institute on Aging (NIA) Special Initiative Grants for research on aging (R-21) announced in the NIH Guide for Grants and Contracts, Vol. 6, No. 21 and Vol. 7, No. 7, is withdrawn. The last receipt date for applications for this award is February 11, 1983.

The Institute has reassessed its support of the Special Initiative Grant and decided that program objectives can be accomplished by other mechanisms of support.

NOTICE

GERIATRIC MEDICINE ACADEMIC AWARD

NATIONAL INSTITUTE ON AGING

Effective immediately, the maximum amount that may be requested for a Geriatric Medicine Academic Awardee's (GMAA) salary is $30,000 per year. This applies to new GMAA applications, and competitive and noncompetitive renewal GMAA applications. This limit replaces the previous maximum of $25,000 for the awardee's salary support for this award.

NOTICE

REMINDER

SUBMISSION OF FORM HHS-596--PROTECTION OF HUMAN SUBJECTS: ASSURANCE/CERTIFICATION/DECLARATION

Under current policy, an applicant organization is responsible for certifying, on form HHS-596, that each non-exempt research activity relating to human subjects described in every application has been reviewed and approved by an Institutional Review Board, as required by 45 CFR 46. An HHS-596 form must be submitted with the application, as clearly indicated in the instructions for form 398 (see page 10 of instructions dated 5/82). However, if the institutional review is unavoidably delayed beyond the submission of the application, enter "pending" on the form HHS-596 and provide an explanation. A follow-up certification on another form HHS-596 must then be submitted and received within 60 days after the receipt date for which the application is submitted. Any modifications of the RESEARCH PLAN section of the application are to be submitted with the follow-up certification. If the certification is not received within this period, the application will be considered incomplete and will be deferred for a later review.

In the past, staff of the Division of Research Grants (DRG) tried to obtain from the principal investigator those HHS-596 forms that did not arrive within 60 days after the receipt date. However, due to limited personnel and heavy workloads, DRG can no longer carry out this practice. It is the responsibility of the principal investigator and the applicant organization to see that the HHS-596 form arrives in a timely manner.

In many instances, the forms arrive late because they are sent to the wrong office. Thus, when the HHS-596 form is not submitted with the completed application, it should be submitted to the Executive Secretary of the initial review group (IRG) to which the application has been assigned for review. Notification of IRG assignment is sent to the principal investigator, except in those instances where NIH is requested by the applicant organization to send notification to a designated official. If the assignment information is unknown at the time a separately-mailed HHS-596 form is submitted, it may be obtained by contacting the following:

Project Control Section
Referral Branch
Division of Research Grants
National Institutes of Health
Westwood Building - Room 253
Bethesda, Maryland 20505

Telephone: (301) 7324

NOTICE

STIPEND INCREASE FOR NRSA TRAINEES AND FELLOWS FOR FISCAL YEAR 1983

There will be a stipend increase for all National Research Service Awards (NRSA) for institutional trainees and individual fellows which is effective immediately for all appointments and awards made in Fiscal Year 1983 (October 1, 1982 - September 30, 1983). This increase will be provided on all grants and awards issued by the National Institutes of Health (NIH), Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), and Health Resources and Services Administration (HRSA)/Division of Nursing. Awards issued for FY 83 prior to the date of this notice will be revised to provide for the new stipend levels. The NIH and the Division of Nursing will implement the stipend increase according to the following guidelines:

1. The 5% increase in stipend allowance is tied to the FY 1983 Budget and therefore should be extended to each trainee or fellow provided for in awards made on or after October 1, 1982. No adjustments will be made retroactively for trainees or fellows either appointed under previous fiscal year institutional NRSAs or included in previous fiscal year individual fellowship awards regardless of whether or not activated. These individuals will receive increased stipend levels associated with their appointments, if any, under FY 1983 awards or beyond.

2. Even though selective prior fiscal year awards may have funds available, those funds may not be used to adjust upward the stipend levels of National Research Service Awardees covered under awards issued prior to FY 1983.

ADAMHA will generally follow these guidelines but will notify their awardees regarding the specific plans for implementation.

The new stipend levels are as follows:

Years of Relevant Experience	New Stipend FY 1983
0	$14,040
1	14,736
2	15,468
3	16,236
4	17,040
5	17,892
6	18,780
7 or more	19,716
Predoctoral	5,292

This notice revises information previously published in the PHS Grants Policy Statement, December 1, 1982 and the NIH Guide for Grants and Contracts - Special Edition Vol. 11, No. 7, June 18, 1982.

NOTICE

HIGHLIGHTS OF REVISED PHS GRANTS POLICY STATEMENT FOR NIH GRANTEES

The revised Public Health Service Grants Policy Statement (DHHS Publication No. (OASH) 82-50,000) was recently published and made available to all Public Health Service (PHS) grantee institutions.

The listing below represents an attempt by the National Institutes of Health (NIH) to highlight selective sections of the revised policy statement which we believe deserve particular attention by both NIH and grantee institution staff in regard to their specific applicability to NIH-supported grant programs. Also included are references to long-standing policies or procedures applicable to NIH grantees which are not covered in the PHS Grants Policy Statement.

Grants from the NIH are to be administered in compliance with the policies published by the PHS except where deviations or modifications have been approved by the Department of Health and Human Services or PHS on behalf of NIH. Such approved variations and any additional NIH implementing instructions or aspects peculiar to NIH will be published routinely in the NIH Guide for Grants and Contracts for distribution to all grantee organizations.

HIGHLIGHTS

1. Page 1 - Effective Date - The revised policy statement is applicable to budget periods beginning on or after December 1, 1982. The earlier PHS Grants Policy Statement, dated October 1, 1976, and the Addenda thereto, continue to apply to active budget periods which began prior to December 1, 1982.

2. Page 6 - Supplemental Applications for Administrative Increases to Meet Institution-Wide Increased Costs - The following long-standing NIH practice remains in force: Where the project is located in an organizational component that receives an NIH Biomedical Research Support Grant, no supplemental funds will be provided by NIH for administrative increases which take effect during a current budget period (such as for funds to cover such increases may be included in the next application for non-competing continuation support.

3. Page 19 -Application Receipt - The Department of Health and Human Services (DHHS) has approved a deviation from the postmark date requirement for grant applications processed through NIH's Division of Research Grants (DRG). The DRG system requires that applications must be received by the published application receipt dates. A package carrying a legible proof-of-mailing date assigned by the carrier, and which is no later than one week prior to the receipt date, is also acceptable. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following work day. The receipt date will

be waived only in extenuating circumstances. To request such a waiver, include an explanatory letter with the signed completed application. No waiver will be granted prior to receipt of the application.

4. Page28 - Alteration and Renovation - The ceiling amount chargeable to PHS grants for any single alteration and renovation project has been raised from $75,000 to $100,000.

5. Page 32 - Entertainment - As cross-referenced to Meals (page 34), deals with unallowability of meals, beverages, etc. in the context of entertainment or social activities.

6. Page 34 - Preaward (Prearrangement) Costs - A new cautionary statement has been added at the end of this section concerning the exercising of this flexibility.

7. Page 34 - Publication Costs - The conditions for paying for page charges in professional journals have been reduced from six to two and eliminates the non-profit requirement for journal publication. Note also the statement regarding the purchase of coverless reprints.

8. Page 35 - Relocation Costs - A new statement has been added at the end of this section addressing the unallowability of personal relocation expenses in change of grantee institution situations.

9. Page 36 - Sabbatical Leave - A new statement has been added at the end of this section concerning 100% maximum compensation for combinations of sabbatical leave allowances and other sources of support (e.g., partial salary from a PHS grant).

10. Pages 36-37 - Salaries and Wages - Although not included in the revised policy statement, DHHS and PHS have assured NIH that there is no intention of changing the following long-standing policy applicable to all research or academic career awards issued by NIH: Funds budgeted in an NIH-supported research or training grant for an individual's salary and/or fringe benefits, but freed as a result of funding a research or academic career award for that individual, may not be used for any other purpose except when the individual no longer participates in the grant supported activity and another individual replaces him/her and requires comparable remuneration. It is incument upon the awardee to inform NIH of any and all research or training salary support freed by a research or academic career award.

11. Pages 39-40 - Travel - For educational institutions only, prior approval for each separate foreign trip is now delegated to the grantee's Institutional Prior Approval System rather than the PHS awarding unit.

12. Page 44 - Methods for Grantees to Request Approvals - A change has been made concerning retroactive approvals for those situations where such approval is required after the period of active PHS grant support. In that circumstance, only PHS awarding unit officials may authorize retroactive approvals, even though the Institutional Prior Approval System originally was delegated the prior approval authority.

13. Page 48 - Grant Related Income - Unless otherwise specified in an award notice, grant related income will be deducted from total allowable costs. Awarding units may, upon request, make changes to other available alternatives with a specific term on the Notice of Grant Award, even during the current budget period.

14. Page 49- Surplus Property - Although not a new provision, the statement concerning the unallowability of providing PHS grantees with excess Federal property has been added to this policy document. Technically, the paragraph which addresses this should be separately headed "Excess Federal Property" as distinct from "Surplus Property."

15. Page 57 - Grant Appeals Procedures - Reference is made to PHS having established a first line of appeal which must be exhausted before an appeal may be made to the DHHS Grant Appeals Board. For NIH grantees, the first line of appeal is the NIH Grant Appeals Board.

16. Page 88 - Appendix VII - A statement has been introduced indicating that PHS will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

17. Pages 90-91 - Appendix VIII - An unequivocal statement is included regarding no indirect costs being provided to Federal grantees nor are Federal grantees required to cost share. A change has been made allowing equipment items costing $1,000 or more originally acquired by the Federal grantee to be transferred to another institution in approved change of grantee institution situations.

18. Page 92 - Appendix IX - This section pertains to for-profit organizations and cites exceptions or differences to usual administrative requirements (e.g., equipment title; single method of cost sharing). Neither here nor elsewhere in this policy document will you find any reference to prior approval authorities for for-profit organizations. To date, PHS has not vested for-profit organizations with the Institutional Prior Approval System or its equivalent; thus, for this class of grantee the awarding unit must, for the present, review all requests that require prior approval.

Note

NIH has recently conferred with PHS concerning the few discrepancies and errors contained in the 1982 edition of the PHS Grants Policy Statement, and learned that PHS will be publishing an addendum which addressess those matters. Further, PHS soon will be issuing a number of Grants Administration Manual chapters which will amplify/clarify a variety of subjects covered in the revised policy statement.

Examples of some of the items to be covered in the PHS addendum are:

1. Page 3 - Glossary. Federal Institution - "Federal hospitals, such as VA hospitals" are not to be excluded from the definition of a Federal institution. Accordingly, as Federal institutions, VA hospitals are subject to

the policies stated in Appendix VIII (pages 90-91). For example, PHS grants made directly to VA hospitals (as with any Federal institution) will not include any indirect cost allowance.

2. Page 7 - A Non-Competing Extension - In the first pargraph, reference to administrative approval by the "Grants Management Officer or the PHS awarding office" should read of the PHS awarding office."

3. Page 32 - Equipment Purchase - The requirement that "PHS awarding office prior approval" be obtained for the purchase of special-purpose equipment costing $1,000 or more per unit is part of a general statement on the subject of equipment purchases and associated prior approvals. The later more-specific material on PRIOR APPROVAL AUTHORITIES (page 45) continues to reflect the long-standing policy which indicates that the method for obtaining such prior approval has, in most cases, been delegated to the grantee institution for treatment under an Institutional Prior Approval System. However, private non-profit grantee institutions other than colleges, universities, hospitals, research institutes and research foundations, must obtain prior approval from the Grants Management Officer of the PHS awarding office for all proposed actions for which prior approval is required.

4. Page 81 - Appendix IV - Reference in the chart to "Appendix B" should instead read "Appendix II."

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NIAID-83-1

ASTHMA AND ALLERGIC DISEASE CENTERS AND ASTHMA AND ALLERGIC DISEASE CENTERS FOR IMMUNODERMATOLOGIC STUDIES

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: October 15, 1983

I. BACKGROUND INFORMATION

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for grants to be initiated during FY 1984 for participation in the ongoing Asthma and Allergic Disease Centers (AADC) programs.

The Allergy and Clinical Immunology Branch of the Immunology, Allergic, and Immunologic Diseases program of NIAID sponsors fundamental and clinical research grants and contracts and the procurement and application of research resource and reference reagents concerned with asthma, allergic and immunologic diseases and with relevant mechanisms of hypersensitivity and inflammation. This request for applications is intended to encourage the development of proposals from clinical investigative groups meeting the criteria and requirements for an AADC and to coordinate the submission of new and renewal applications providing equitable opportunity for both to compete for funds currently available for this programmatic activity.

Since its inception in 1971, the AADC program has progressively expanded with the gradual addition of new Centers on an open application basis. In accordance with established policy announced in the NIH Guide for Grants and Contracts, Vol. 7, No. 8, p.1, June 9, 1978, proposals for AADCs are received only periodically and at designated times. Applications for both renewal of existing AADCs and creation of new Center programs will be expected to compete for funds available through the periodically announced awards.

The AADC program currently consists of 17 centers. It should be emphasized that within the AADC program, two immunodermatology centers were awarded in 1980. These are now part of the overall program and are subject to competitive renewal. During FY 1984, two Centers are scheduled to terminate and may compete for renewal.

This program is described in the Catalog of Federal Domestic Assistance No. 13.855, Immunology, Allergic and Immunologic Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under Public Health Service grant policies and Federal Regulation 42 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

NIAID's fundamental objective in continuing the AADC program remains unchanged: acceleration of the application of emerging knowledge on the immune system and from relevant biomedical sciences to clinical investigations concerned with asthma, allergic diseases, and hypersensitivity disorders. Especially sought as the requisite factors within a participating institution are quality research in (a) basic science(s), (b) clinical investigation supported by adequate clinical facilities, staff expertise in diagnosis and management of asthmatic and allergic patients, and (c) access to (an) appropriate patient population(s) within a suitable academic/investigative setting designed to favor multidisciplinary interaction.

II. RESEARCH GOALS AND SCOPE

A. There should be indication by the sponsoring university or medical institution of willingness and preparedness to commit resources to ensure development, operation, support, and function of the proposed Center in devoting its efforts to an identified study on asthma and/or allergic disease as a fundamental prerequisite.

B. The applicant's achievements in basic science research should have reached that stage of development where experimental leads are sufficiently encouraging to warrant transition from promising laboratory findings to corresponding investigations at the clinical level with the ultimate goal of developing new and improved methods for diagnosis, prevention, and treatment of asthma and/or the other allergic diseases.

C. A prospective Center should be in a position to present evidence of experience, orientation, laboratory and clinical facilities, scientific and professional staff, support personnel and the expertise to design proposals, execute protocols representing a multifaceted long-term approach, and bring diverse institutional strengths to bear upon the study of major problems in asthma, other allergic diseases and/or pathophysiologic mechanisms underlying these disorders.

D. Suitable subjects for study within the provision of this program may include those relevant to:

1. asthma and its multifactoral aspects;

2. atopic diseases (e.g., allergic rhinitis, urticaria, atopic dermatitis);

3. identification, isolation, and characterization of etiologic agents of allergy (e.g., drugs, chemicals, foods, airborne allergens);

4. pathologic expressions, pathophysiologic mechanisms, and genetic factors of allergic disease and allergic inflammation;

5. immune mechanisms and agents of immediate hypersensitivity and of related hypersensitivity manifestations of antigen-antibody reactions of cell mediated immunity (e.g., hypersensitivity pneumonitis, allergic dermatitis, vasculitis, allergic gastroenteritis, drug reactions) and the development of corresponding improved diagnostic materials and methods;

6. immunopharmacology, immunotherapy, and the development of specific pharmacologic agents designed for prevention and treatment of asthma and the other allergic diseases.

7. immunodermatologic studies; the role of hypersensitivity and immune-related inflammatory mechanisms has become increasingly evident in disorders of the skin. The recognition of the socio-economic impact of allergic skin disorders has provided another stimulus to further major efforts in this field. Clinical immunologists are in a position to take advantage of the ready access of the skin for in vivo studies of immune mechanisms operative in both local lesions and systemic immunopathologic disease with manifestations at cutaneous sites. NIAID views which favor the entrance of researchers from immunobiology, immunochemistry, and immunogenetics into clinically relevant studies leading to advances in the diagnosis, prevention, and treatment of allergic and immunologic diseases. These studies in skin diseases may be conducted at an AADC with special emphasis on immunodermatology.

E. Study of animal models will be considered acceptable as a partial segment or adjunct to a Center's program only if this line of research is applicable to the character of the primary investigation of asthma or the human allergic disease central to the proposal.

F. Designation of a Center Director should be based upon accomplishment and experience as a senior scientist and ability to assume both leadership of the investigative group and responsibility for scientific, professional, and administrative functions.

G. More than one delineated avenue of research may be pursued within a Center with provision for unified operation and coordination of component projects and collaborative investigators.

H. A Center should not rely upon its ability to conduct research activity solely within the confines of a single discipline, but rather should have established the associations to involve participation by workers in the pertinent biomedical fields and medical specialties allied to asthma, allergy, and clinical immunology (e.g., immunobiology, biochemistry, microbiology, biostatistics, bioinstrumentation and computer science, and the clinical subspecialities, e.g., dermatology, rheumatology, infectious diseases, pulmonary medicine, hematology, otorhinolaryngology, when a high degree of relevance to immunology exists.

I. The Center Director will be expected to communicate freely with the NIAID and other designated Centers for effective exchange of new information, to interact with scientists working in other Centers on related investigative problems, and to present progress reports and share experimental data with other Centers through exchanges and attendance at NIAID sponsored meetings of study group and AADC workshops.

III. MECHANISM OF SUPPORT

In fiscal year 1984, the NIAID plans to fund at least two new or competing renewal AADC applications. Each grant will have a duration of not more than five years.

Funding beyond the first year of the grant will be contingent upon satisfactory progress during the preceding year and availability of funds.

The receipt date for applications will be October 15, 1983. They will undergo initial review in February-March 1984, and subsequent review by the National Advisory Allergy and Infectious Diseases Council in May 1984. September 1, 1984 will be the earliest starting date for successful applicants.

Grant funds may be utilized to support the research activities of scientific and professional personnel, consultation services, equipment, supplies, travel, and publication costs. Support for research-related costs of patient involvement and medical care may be authorized. Since the program cannot provide funds for new construction, adequate physical facilities must be available for the primary needs of the Center. However, moderate alterations or renovations to enhance clinical facilities may be allowed if they are necessary to meet objectives of the Center's program.

Only those institutions that can demonstrate expertise in both basic and clinical areas and can direct their resources toward a multifaceted attack on asthma or the other allergic diseases can be supported under the provisions of the AADC program.

IV. LETTER OF INTENT

Prospective applicants are encouraged to submit to the Chief, Allergy and Clinical Immunology Branch, NIAID, a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institutions. The Institute requests such letters for the purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding, it will not enter into the review of any application subsequently submitted, and is not a necessary requirement for application.

Inquiries should be directed to:

Dr. Robert A. Goldstein
Chief, Allergy and Clinical Immunology Branch
Immunology, Allergic and Immunologic
Diseases Program
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 755
Bethesda, Maryland 20205

Telephone: (301) 496-7104

V. REVIEW PROCEDURES AND CRITERIA

These are outlined in the NIAID Information Brochure on Program Projects (see "METHOD OF APPLYING" below).

VI. CONSEQUENCES OF LACK OF RESPONSIVENESS TO THE RFA OR LATE SUBMISSION

Based upon the letter of intent, potential applicants will be promptly advised whether or not their proposal is found to be within the research goals and scope of the program as defined in this RFA. Applicants will then have an opportunity to correct deficiencies or weaknesses and to restructure their submissions accordingly. Formal applications that are not responsive to the RFA or are not received by October 15, 1983, will not be accepted for review and will be returned to the applicant.

VII. METHOD OF APPLYING

Before preparing an application, the prospective applicant should request a copy of the NIAID Information Brochure on Program Projects from:

Dr. Nirmal Das
Executive Secretary
Allergy, Immunology and Transplanation
Research Committee
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 706
Bethesda, Maryland 20205

Telephone: (301) 496-7966

The Information Brochure contains special instructions for preparing program project grant applications, review procedures and criteria, and other important information.

Use the standard research grant application form PHS 398 (Rev. 5/82). In addition to following accompanying format instructions for the development of a Center application, include expanded material listed above under the eight points for the "letter of intent." For purposes of identification and processing, the words "ASTHMA AND ALLERGIC DISEASE CENTER" should be typed in item 2 on the face page of the application and a brief covering letter should be attached indicating submission is in response to this NIAID announcement.

Application kits may be obtained from the institution's application control office. If not available there, they may be obtained from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 448
Bethesda, Maryland 20205

Forward the complete application to:

Division of Research Grants
National Institues of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Please forward a copy (not the original) of the cover letter and the application face page to:

1. Dr. Robert A. Goldstein, in order to alert NIAID to the submission of the proposal, and

2. Chief, Program and Project Review Branch
   National Institute of Allergy and
   Infectious Diseases
   National Institutes of Health
   Westwood Building - Room 703
   Bethesda, Maryland 20205

ANNOUNCEMENT

COTTON-TOPPED MARMOSET COLONY

NATIONAL CANCER INSTITUTE

This announcement is being issued to inform investigators of the availability of a colony of cotton-topped marmosets Saguinus oedipus oedipus and a holding facility for experimental animals where researchers can conduct cancer research.

The Biological Carcinogenesis Branch, Division of Cancer Cause and Prevention, supports a colony of cotton-topped marmosets Sanguinus oedipus oedipus at Oak Ridge Associated Universities (ORAU) under NCI contract N01-CP2-1004. Under the contract, ORAU operates a breeding colony of cotton-topped marmosets; operates a containment holding facility that houses experimental marmosets; and provides experienced professional and technical personnel who will work with investigators to carry out their protocols. The individual investigators request animals and services to conduct studies on cancer research. In return the researchers will be charged a per diem cost of $1.78 per day for adults and $16.50 for experimental newborns held in the nursery. This fee includes housing the animal, collection of specimens and minor surgery. Other services available for a fee are biopsy, necropsy, bone marrow differential count, blood chemistry profile and individual blood chemistry tests.

Investigators interested in making use of this service should contact:

Dr. Harry Walburg
Director, Comparative Animal Research Laboratory
Oak Ridge Associated Universities
P.O. Box 117
Oak Ridge, Tennessee

Telephone: (615) 576-4000

ANNOUNCEMENT

TRANSFUSION MEDICINE ACADEMIC AWARDS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: May 1, 1983

The Division of Blood Diseases and Resources (DBDR), National Heart, Lung, and Blood Institute (NHLBI), announces a national competition for Transfusion Medicine Academic Awards to encourage the development of a teaching focus in transfusion medicine and to further the development of trained personnel who can serve the research and clinical needs of transfusion medicine. Each school of medicine or osteopathy in the United States or its possessions and territories is eligible. (Awards are limited to one for each eligible school, for a project period of up to five years, and are not renewable.)

For the purposes of the Tranfusion Medicine Academic Award, the term "transfusion medicine" is used to define a multidisciplinary area concerned with the proper use or removal of blood and its components in the treatment or prevention of disease states (other than in renal hemodialysis).

The DBDR is initiating the Transfusion Medicine Academic Award Program to encourage the coordination of subject matter for teaching programs in transfusion medicine. Presently, there is rarely a formal mechanism whereby teaching, clinical, and research responsibilities in transfusion medicine can be coordinated by knowledgeable professionals into programs. These components of transfusion medicine are usually dispersed among basic and clinical science disciplines and among activities of the local transfusion services or blood center facility. The teaching of transfusion medicine may not require additional curriculum time. Existing teaching materials (components of other disciplines) may be coordinated into an overall program and organized to focus on emerging and important areas of transfusion medicine. Some schools may find it desirable to assemble the appropriate components into a specific transfusion medicine unit. Others may wish to retain the transfusion medicine discipline as part of another major clinical or laboratory department. Awards provide support to experienced investigator-faculty members, who are skilled organizers and negotiators, for their educational development in transfusion medicine and for implementation of the transfusion medicine curriculum.

This program is described in the Catalog of Federal Domestic Assistance No. 13.839, Blood Diseases and Resources. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 73-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

This award is intended to:

- encourage the development of effective multidisciplinary curricula in transfusion medicine that will attract outstanding students to transfusion research and clinical practice;
- attract and develop faculty who will have a major commitment to research and teaching in transfusion medicine;
- attract promising young physicians and scientists into careers in clinical and research aspects of transfusion medicine;
- facilitate interchange of information and educational techniques among research, medical, and blood service communities; and
- develop, at the grantee institution, the ability to continue to improve the transfusion medicine program, with local funds, subsequent to the award.

Applications must be received by May 1, 1983, for review of the September 1983 meeting of the National Heart, Lung, and Blood Advisory Council. Awards will be made by September 30, 1983 at the earliest.

To receive a copy of the Program Guidelines, please contact:

Fann Harding, Ph.D.
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 5A08
Bethesda, Maryland 20205

Telephone: (301) 496-1817

ANNOUNCEMENT

SCHOOL HEALTH PROMOTION AND CARDIOVASCULAR HEALTH OF CHILDREN AND ADOLESCENTS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The Preventive Cardiology Branch (PCB) of the National Heart, Lung, and Blood Institute (NHLBI), encourages interested investigators to submit research grant applications in the area of demonstration and education research in cardiovascular school health promotion. The proposed research should address the identification of precursors and determinants of the development and maintenance of behaviors in children and adolescents conducive to cardiovascular health (sound nutrition, non-smoking, physical activity, and other areas).

Cardiovascular disease continues to be the leading cause of death in the United States, although there has been a downward trend in age adjusted mortality for coronary heart disease and stroke. Individual lifestyles are associated with characteristics which increase the risk of cardiovascular diseases. For example, cigarette smoking is strongly associated with coronary heart disease. Obesity is correlated with development of hypertension, hyperlipidemia, and diabetes. A diet high in saturated fats, cholesterol, and calories is correlated with hyperlipidemia and excess consumption of calories and physical inactivity usually results in overweight.

The problem of cardiovascular disease is not solely a problem of the adult population. The atherosclerotic process may begin in childhood in susceptible individuals and progress during adolescence and young adulthood even though serious clinical manifestations usually do not appear until middle age or later. Efforts to prevent or retard this process may, therefore, be directed at children as well as adolescents and adults.

This comprehensive school health program is one approach for investigating the determinants of good cardiovascular health habits and their maintenance in early preschool through high school age groups. During the early years health behavior, in general, is influenced predominantly by the family within a social environment. As children mature, they are influenced by a more complex set of factors such as peers, society, media, and school programs. A comprehensive school health program consists of school health education*, school health services, school health environment, and the interaction with community agencies and families. While some examples of good school

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This program is described in the Catalog of Federal Domestic Assistance No. 13.837, Heart and Vascular Diseases Research. Awards will be made under the authority of the Public Health Services Act, Title III, Section 301 (Public Law 73-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

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*Health Education
Any combination of learning opportunities designed to facilitate voluntary adaptions of behavior (in individuals, groups, or communities) conducive to health.

health programs exist in the country, the area of comprehensive school health programs and school health promotion* need further research to maximize the potential for encouraging children and adolescents to develop healthy cardiovascular lifestyles.

The objective of this program announcement is to encourage research activities into factors which may have a significant contribution to the role of school health promotion and the adoption of behaviors conducive to good cardiovascular health in children and adolescents. The following areas of research are of major interest:

1. Identification and evaluation of the interactive effects of the major variables that might be determinants of the development of cardiovascular health behaviors in children and adolescents. Some of the variables that might be assessed in the interactive models are the school health curriculum, the school health enviornment, school health services and school food service programs, as well as the influence of teachers, families, peers, media, and relevant community organization and services.

2. Identification and evaluation of the developmental stages for the acquisition of positive and negative cardiovascular health behaviors and the optimal age groups and health education strategies for teaching health education related to the major cardiovascular health areas and for reinforcement for maintenance of behaviors.

3. Investigation of the predisposing, enabling, and reinforcing factors that influence cardiovascular-related health behaviors for specific populations of children and adolescents that may be high risk groups.

4. Determination and evaluation of the significant variables related to the diffusion and implementation of cardiovascular health promotion programs in schools and analysis of the effectiveness and cost of the dissemination.

5. Develoment of new instruments or validation of existing methods for assessing knowledge, attitudes, and behaviors related to cardiovascular health areas for the different age groups of children and adolescents.

This list is intended to provide examples only and does not preclude the submission of applications involving other research approaches which may have importance for cardiovascular school health promotion.

Investigators may study the role of one or more factors in the promotion of cardiovascular healthful lifestyles. However, since prevention in this area is a multi-faceted problem, investigators are encouraged to study the implications of several interacting factors for prevention activities. Innovative designs may be able to be used with relatively small-scale studies in which there has been careful selection of variables and study participants with a well-developed conceptual framework. These suggestions are not intended to limit research designs or the scale of the studies, but to stress that

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*Health Promotion
Any combination of health education and related organizational, political, and economic interventions designed to facilitate behavior and environmental adaptions that will improve or protect health.

careful attention be paid to the study design. Investigators are encouraged to use interdisciplinary approaches for their proposed research. The investigators should demonstrate an indepth knowledge of the state-of-the-art research in the areas of cardiovascular health as it relates to the research population. If self report instruments are used, the study design should include biochemical or physiological measurements to increase the validity of self-report data. The study design may be descriptive, correlational, experimental, or a combination of several types of research designs as appropriate for the research proposed.

I. MECHANISMS OF SUPPORT

Support for this research is available through investigator initiated research grants.

II. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Applications sent in response to this program announcement will be reviewed in accordance with the NIH peer review procedure. If an application submitted in response to this program announcement is identical to a research grant application already submitted to the National Institutes of Health (NIH) for review, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed.

B. Review Criteria

The criteria for review are the traditional considerations underlying scientific merit which include adequacy and appropriateness of the application; training, experience, and research competence of the investigator(s); the adequacy of the research design; description of the research population; rationale for method of sampling; definition of the variables; the suitability of the facility; evidence of the likelihood of access to and cooperation from the participant population, and the appropriateness of the requested budget relative to the work proposed.

III. METHOD OF APPLYING

A. Letter of Intent

Applicants are encouraged to submit a letter of intent at least 45 days prior to formal submission of an application. Include the name of the principal investigator, institution address, an abstract of the proposed research, and indicate that the application is in response to this announcement. The Institute requests such letters for the purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding, and it will not enter into the review of any application subsequently submitted, nor is it a necessary requirement for application. The letter of intent and requests for additional information should be sent to:

Dr. Elaine J. Stone
Preventive Cardiology Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 6A12
Bethesda, Maryland 20205

Telephone: (301) 496-2465

B. Application Procedure

Receipt dates for applications submitted in response to this announcement are the usual dates for investigator-initiated research grant applications of March 1, July 1, and November 1. Grant applications should be submitted on form PHS 398 (Rev. 5/82). If these forms are not available in the business or grants and contracts office of your institution, copies may be obtained from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7441

In order to identify the application as a response to this program announcement check "yes" on Item 2 of the application face page and enter the title "SCHOOL HEALTH PROMOTION AND CARDIOVASCULAR HEALTH." Attach a cover letter indicating that this application is in response to this announcement. The original application and six copies with the cover letter should be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

An additional copy of the application should be mailed to Dr. Elaine J. Stone.

☆ U.S. GOVERNMENT PRINTING OFFICE: 1983-381-144:211

NIH Guide
for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 12, No. 2, February 25, 1983

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(Continued)

The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE TO SMALL BUSINESS

SMALL BUSINESS INNOVATION RESEARCH PROGRAM (SBIR)

As a result of many discussions with representatives of research oriented small businesses, the Public Health Service (PHS) has determined that potential applicants would benefit from additional time to prepare grant applications for the Small Business Innovation Research (SBIR) program. Therefore, the PHS announces that the first receipt date for SBIR applications has been changed from March 15, 1983 to May 1, 1983.

ERRATUM

HIGHLIGHTS OF REVISED PHS GRANTS POLICY STATEMENT FOR NIH GRANTEES

A Notice in the January 29, 1983, NIH Guide for Grants and Contracts (Vol. 12, No. 1) printed on page 4, had a sentence omitted from paragraph 2 under HIGHLIGHTS. The correct paragraph 2 should read as follows:

> "2. Page 6 - Supplemental Applications for Administrative Increases to Meet Institution-Wide Increased Costs - The following long-standing NIH practice remains in force: Where the project is located in an organizational component that receives an NIH Biomedical Research Support Grant, no supplemental funds will be provided by NIH for administrative increases which take effect during a current budget period (such as institution-wide salary and/or fringe benefit increases). A request for funds to cover such increases may be included in the next application for non-competing continuation support."

NOTICE

NATIONAL CANCER INSTITUTE

The National Cancer Institute will resume accepting new and competing renewal applications for the clinical cancer education program grants (R25). Next receipt date will be June 1, 1983. For copies of the new guidelines contact:

Dr. Olga G. Joly
Program Director, CCEP, DRCCA
National Cancer Institute
Blair Building - Room 722
8300 Colesville Road
Silver Spring, Maryland 20910

Telephone: (301) 427-8855

SITE VISITS TO ANIMAL CARE FACILITIES

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH) is embarking on a series of site visits to randomly selected awardee institutions to assess the adequacy of the current process for promoting proper care and use of animals in the biomedical research which NIH funds.

In particular, the visits are intended to determine whether or not the facilities, systems, and practices for the care and use of laboratory animals are consonant with the statements of assurance now on file with the NIH.

The information gathered will be valuable for addressing three overriding questions: Is the present assurance system adequate? Even if adequate, how can it be improved? If inadequate, what other approaches should be explored?

I. BACKGROUND

As a part of its overall mission to fund high-quality biomedical research and research training, the NIH has an obligation to promote the appropriate care and use of laboratory animals. Since 1971, the NIH has required awardee institutions which conduct experiments with laboratory animals to submit written statements of assurance committing themselves to follow the principles set forth in the NIH Guide for the Care and Use of Laboratory Animals as well as all federal, state and local statutes relating to laboratory animals. In addition, many institutions have sought and received accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC).

As a matter of policy, the NIH negotiates these assurance statements carefully but has made no systematic effort to assess compliance unless concerns are raised by: (a) peer reviewers and/or staff during the normal processes of evaluating applications, proposals, and progress reports, (b) individuals or groups who submit evaluable allegations, and/or (c) authorized inspection, such as performed by the United States Department of Agriculture under the Animal Welfare Act of 1966 (as amended). In recent years, critics of NIH policies have questioned the adequacy of the assurance process both in concept and in relation to a few specific instances of actual or apparent failure by awardees to ensure appropriate practices. Because of the need to maintain public confidence in science and in the officials who administer Federal funds, the NIH has decided to examine its assurance system.

II. APPROACH

The effort is being conducted under the leadership of the Office of Extramural Research and Training (OERT). NIH staff and advisors have developed a protocol for conducting the site visits. The first group of institutions will be visited during the period March through September 1983. Visits will be made to a stratified, random sample of ten institutions which operate under approved assurances but which do not have accreditation from the AAALAC. The institutions will be selected according to the following plan: (a) one institution will be chosen from each of the ten Department of Health and Human Services geographic regions, and (b) three or four institutions will be taken from each of three categories of total annual NIH support of more than $10 million, $5-10 million, and less than $5 million

Each site visit team will be composed of several members (usually 3-5), comprising NIH employees and non-federal consultants. A member of the NIH staff will notify the appropriate institutional representative(s) about one month before the scheduled visit.

Additional information concerning this notice may be obtained from:

Dr. Louis R. Sibal
Office of Extramural Research and Training
National Institutes of Health
Shannon Building - Room 314
Bethesda, Maryland 20205

Telephone: (301) 496-4716

NOTICE

PERIOD FOR INDIVIDUAL NRSA FELLOWSHIP ACTIVATION REDUCED

A recent policy decision by the Public Health Service (PHS) has reduced the maximum period of time for activation of Fellowship awards from twelve months to six months. The activation period is that period of time from the initial award of an individual NRSA fellowship, to the actual initiation of the fellowship experience. Previously, fellows have been permitted up to a maximum of twelve months following award to begin their fellowship. Effective for new fellowship awards issued in the Government's fiscal year 1983 (October 1, 1982 - September 30, 1983), the maximum activation period is six months. Extensions of the activation period may be granted for good reason. Recipients of NRSA fellowship awards are encouraged to keep the awarding units of the National Institutes of Health (NIH), Alcohol, Drug Abuse and Mental Health Administration (ADAMHA), and the Health Resources and Services Administration (HRSA) Division of Nursing, well-informed of their activation plans.

This notice revises and updates information published in the PHS Grants Policy Statement dated December 1, 1982 and NIH Guide for Grants and Contracts, Vol. 11, No. 7, June 18, 1982 Special Edition, "National Research Service Awards Guidelines for Individual Awards - Institutional Grants." Questions on this issue may be addressed to staff of the awarding unit as identified on the Notice of Fellowship Award.

NOTICE

AVAILABILITY OF CONGENIC MOUSE STRAINS

NATIONAL CANCER INSTITUTE

This announcement is being issued to inform investigators of the availability of strains of congenic mice representing discriminative alleles of genes of special interest in viral leukemogenesis.

The Biological Carcinogenesis Branch, Division of Cancer Cause and Prevention, supports a congenic mouse production facility at Sloan-Kettering Institute for Cancer Research under NCI contract N01-CP7-1003. At present there are 14 strains of congenic mice in various stages of development and 2 Gix-gp70 mutant strains. The gene substitutions involved include Akvp, Fv-1, Gv-1, Gv-2, H-2, Pca-1 and Tla. In several cases, reciprocal substitutions of alleles have been effected between inbred strains that differ categorically in one or more characteristics pertaining to leukemia or leukemia virus providing a quartet of inbred strains, two standard and two congenic with switched alleles, for each gene system.

There is a charge for the animals and the shipping costs are the responsibility of the recipient. For further information please contact:

Dr. Edward A. Boyse
Sloan-Kettering Institute for Cancer Research
1275 York Avenue
New York, New York 10021

Telephone: (212) 794-7500

NOTICE OF AVAILABILITY - RFA

COOPERATIVE AGREEMENTS FOR ORPHAN DRUGS AND MEDICAL DEVICES RESEARCH

FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration will soon announce in the Federal Register the availability of funds for Fiscal Year 1983, for the award of cooperative agreements to support clinical trials on the safety and effectiveness of orphan drugs and medical devices.

Approximately 20 to 80 awards will be made in the range of $20,000 to $100,000 each. Applications must be submitted on form PHS 398, Public Health Service Research Grant Application.

A Request for Application (RFA) is to be published in the Federal Register in February announcing the details.

For further information, contact:

Office of Orphan Products Development
Parklawn Building - Room 12-11
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4903

ANNOUNCEMENT

RFA: EXPLORATORY GRANTS FOR DIGESTIVE DISEASES CORE CENTERS

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Application Receipt Date: May 16, 1983

The National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDK) invites applications for Exploratory Grants for Digestive Diseases Core Centers to be initiated in Fiscal Year 1983.

The objective of the Exploratory Grant is to provide partial support for the planning phase of a Digestive Diseases Core Center. The planning phase may consist of, but is not limited to:

a. departmental and interdepartmental planning to integrate a broad spectrum of digestive disease related activities;

b. planning the establishment of specialized resources and facilities;

c. feasibility surveys to identify appropriate patient populations, identify special problems and opportunities, etc.;

d. use of consultants to solidify plans for Center activities and core resources.

The Core Center must include clinically relevant research focused on the cause, diagnosis, early detection, prevention, control and treatment of digestive diseases and related physiological, pathophysiological, congenital or metabolic disorders resulting from such diseases. This represents a change from the original program in Digestive Diseases and Nutrition Centers announced in 1973, which were Specialized Centers of Research in specified areas (obesity, peptic ulcer and hepatitis and cirrhosis).

NIADDK expects to award no more than eight Exploratory Grants for Digestive Diseases Core Centers in FY 83 on a competitive basis. Direct costs cannot exceed $25,000 each. The anticipated awards are contingent upon the availability of appropriated funds. It is anticipated that successful applicants would be prepared to apply for a Digestive Diseases Core Center in FY 84 or FY 85. The general description of a Core Center, the format of the application for the Exploratory Grant, and the review criteria for such applications are presented on the following pages. The special receipt date for submission is May 16, 1983, with earliest funding September 26, 1983.

This program is described in the Catalog of Federal Domestic Assistance No. 13.848, Digestive Diseases and Nutrition. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

I. Objective

The objective of the Exploratory Grant is to provide partial funding for the cost of planning and developing a high quality Digestive Diseases Center. Successful Exploratory Grant applications will be funded in amounts not to exceed $25,000 direct cost for a 12-month period. Under certain circumstances a no-cost extension of up to another 12 months can be requested. The anticipated Core Center awards are contingent upon authorization and appropriation of funds.

It is important to note that the award of an Exploratory Grant does not imply a commitment by the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases to future funding of any Digestive Diseases Center planned with the support of such an Exploratory Grant. Center applications are reviewed on the basis of their own merit. A future announcement will be made for applications for Digestive Diseases Core Center grants, at which time any applicant may apply, and be funded whether or not they previously had an Exploratory Grant.

II. Background and Rationale

The Centers component of the Digestive Diseases Program of the NIADDK is being expanded at the recommendation of the National Digestive Diseases Advisory Board. The Digestive Diseases Centers will be charged to develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of Digestive Diseases and related physiological, pathophysiological, congenital or metabolic disorders resulting from such diseases.

The type of Center to be planned initially will be a Core Center. The Core Center grant is a mechanism designed to enhance and extend the effectiveness of a group of related projects and investigators that are already funded through other mechanisms such as Research Project Grants or Research Program Projects. In this respect the Core Center mechanism builds upon an established base of research excellence. The Core Center grant may provide funds for: (1) core resources such as tissue culture, immunoassay or biostatistics units which must be utilized by at least two or more Center participants, (2) pilot/feasibility projects to encourage new investigators or investigators from other fields to pursue new and innovative ideas to a point where they can compete for independent support and (3) program enrichment to provide for small conferences or symposia, special consultants and temporary salary support for a "new" investigator. This temporary salary support can be requested for one individual at a time for a period of up to 24 months in specified areas of research complementary to ongoing activities of the group. "New" refers to recently trained investigators. The Core Center does not provide funds for ongoing major research projects of established investigators. A Core Center application must include clinically relevant research in which the focus can be a disease (pancreatitis, functional bowel disease, inflammatory bowel disease, chronic hepatitis), an organ (liver, esophagus, large bowel), a process (absorption, secretion, motility), or an appropriate combination thereof which may also include areas of relevant technology.

Guidelines are available from the NIADDK that describe the Core Center and the application process. These guidelines should be requested before applying for an Exploratory Grant.

In the future, after a strong research and training base of the Core Center becomes well developed, and the Center administrative structure can support additional functions, it is the intention of the Digestive Diseases Program to allow further expansion of Center activities. This expansion will provide an opportunity for the Core Center to convert, on a competitive basis, to a Comprehensive Center and to support new activities in the area of education and information for physicians and paramedical personnel, for patients and their families and for the general public. It may also consider model programs for cost effective and preventive patient care. The NIH will make a further announcement when such Comprehensive Centers may be submitted for review.

III. Criteria for Eligibility

Institutions that are planning to apply for a Digestive Diseases Core Center for the first time are eligible to apply for an Exploratory Grant. An institution that already has a Digestive Diseases Center and plans to submit a renewal application for the same type of center is not eligible to apply for an Exploratory Grant.

IV. Application Procedures and Guidelines

A. For the proper development of an application for an Exploratory Grant for a Digestive Diseases Core Center, the institutional representatives should contact:

Dr. Kirt Vener
Esophageal, Gastric and
Colonic Diseases
NIADDK
Bethesda, Maryland 20205

Telephone: (301) 496-7821

Dr. G.G. Roussos
Intestinal and Pancreatic
Diseases
NIADDK
Bethesda, Maryland 20205

Telephone: (301) 496-7121

Dr. Sarah C. Kalser
Liver Biliary Diseases
NIADDK
Bethesda, Maryland 20205

Telephone: (301) 496-7858

Such contacts should be made during the early planning stages of grant application.

B. The application should include the following:

1. Title

The title of the grant application should be "Exploratory Grant for a Digestive Diseases Core Center."

2. Format of Application

Applications must be submitted on form PHS-398 which is available at most institution business offices or from the Division of Research

Grants, NIH. The application should contain information on the following points:

a. Goals and objectives of the planning effort.

b. Relevance of the Core center being planned to the Digestive Diseases Program.

c. Institutional organization to implement the goals of the planning effort.

d. Listing of the programs (sponsored research) to be included in terms of the utilization and expansion of ongoing activities and inauguration of new projects.

e. Interrelationship with other institutions, if any, and with the scientific and medical communities.

f. Description of the effect that establishment of a Core Center directed towards research in digestive diseases will have on the internal structure or organization of the institution.

3. Grant Amount and Project Period

A maximum of $25,000 direct cost for 12 months is allowable. If necessary, an extension of the initial budget period will be allowed, if adequately justified.

4. Allowable Costs

a. Salaries for staff.

b. Travel required to carry out the planning effort.

c. Supplies.

d. Other related costs.

e. Payment of consultant and technical assistance needed for feasibility surveys, identification of special problems and opportunities for expansion of scientific staff and activities, cost estimates, evaluation of existing space, conceptual design, etc., but not for the development of detailed architectural plans and specifications.

f. Indirect costs.

g. ALTERATION AND RENOVATION ARE NOT ALLOWED.

V. Review Criteria

Applications for Exploratory Grants for Digestive Diseases Core Centers will be evaluated in national competition by the NIH grant peer review process. Applications will be reviewed initially by a special review committee convened by the NIADDK, and subsequently by the National Arthritis, Diabetes, and Digestive and Kidney Diseases Advisory Council. During this process, applications will be evaluated on the basis of the following review criteria:

1. Clarity and appropriateness of the applicant's planning effort, including goals, definition and scope.
2. Applicability of the proposal to the Digestive Diseases Center Program.
3. Composition and competence of the planning Group.
4. Adequacy of applicant's consideration of the following factors:
    a. Patient load and referral patterns.
    b. Staff recruitment.
    c. Needs and utilization of space, including space for recruitment of appropriate personnel.
    d. Financial resources.
    e. Scope of projects
5. Applicant's commitment to digestive diseases programs:
    a. Background of the applicant organization's commitment to digestive diseases programs (program contact, personnel, facilities, financial obligations and commitments).
    b. Current priority of the program within the organization in commitment of personnel, facilities and funds.
6. Planning director:
    a. Background, training and experience.
    b. Leadership, scientific and administrative capabilities, and potential for development.
    c. Commitment to the digestive diseases program, burden of other duties, etc.
    d. Authority in relation to recruitment, staff appointments and promotions, space, fiscal and administrative, review and direction of the planning effort.
7. Research competency and multidisciplinary interests of staff in place or to be recruited.

8. Administration, organization and management capabilities of the applicant organization (letters of agreement from associated institutions).

9. Intellectual environment of applicant organization:

   a. Ability to recruit required talent.

   b. Success in developing similar programs.

   c. Continuity of leadership

VI. Reporting Requirements

As with research grants, terminal progress reports must be submitted to the NIADDK in accordance with the current PHS Grants Policy Statement. Terminal project reports are due no later than 90 days following the end of the project period. In addition, consultation with NIADDK program staff is encouraged throughout the course of the grant period.

VII. Submission of Applications

A special deadline of May 16, 1983, has been established for the receipt of applications in order that applications which are recommended for approval may be eligible for funding during the present fiscal year (FY 83). Final review will be in September with earliest funding September 26, 1983. The original and six copies of each application should be mailed to the Division of Research Grants. An address label is included in the form PHS 398 kit. One additional copy should be mailed to:

Associate Director
Extramural Activities
National Institute of Arthritis, Diabetes
and Digestive and Kidney Diseases
Bethesda, Maryland 20205

VIII. Staff Contacts

For further information, prospective applicants are encouraged to contact the staff members listed under IV.A.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NIAID-83-2

PROGRAM PROJECTS IN MECHANISMS OF IMMUNOLOGIC DISEASES

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: October 15, 1983

I. BACKGROUND INFORMATION

The Allergy and Clinical Immunology Branch of the Immunology, Allergic and Immunologic Diseases Program of NIAID is concerned with asthma, allergic, and immunologic diseases and with relevant mechanisms of hypersensitivity and inflammation. This request for applications (RFA) is intended to encourage the development of proposals from collaborative basic science and clinical investigative groups, and to coordinate the submission of new and renewal program project applications providing equitable opportunity for both to compete for funds currently available for existing programmatic activities concerned with the study of mechanisms of immunologic diseases. As such, this program is intended to complement the Branch's Asthma and Allergic Disease Center program as well as the Centers for Interdisciplinary Research in Immunologic Diseases program.

Immunologic diseases together with asthma, allergic diseases, and hypersensitivity and inflammatory disorders constitute major areas of endeavor of the Allergy and Clinical Immunology Branch. The programmatic activity on immunologic diseases is designed to further investigate underlying mechanisms of disease and to enhance basic knowledge relevant to the etiology, prevention, and management of immunologic disorders. Studies are effected from either one of two disciplinary approaches: clinical immunology or immunopathology. Clinical immunology studies are directed toward acquired and inherited diseases associated with dysfunctions of the immune system. Immunopathology studies include specific areas of genetics, cytology, biochemistry, physiology, and pharmacology of the immune system and its disorders.

The research to be supported by this announcement is concerned with and seeks to define the etiologic factors, pathogenic mechanisms, development of critical diagnostic measures and approaches to effective prevention, control, and treatment of immunologic abnormalities.

This program is described in the Catalog of Federal Domestic Assistance No. 13.855, Immunology, Allergic and Immunologic Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

II. RESEARCH GOALS AND SCOPE

A. Program project grants are awarded to an institution on behalf of a program director for the support of a broadly based, multidisciplinary, long-term research program which has a specific major objective or basic theme. A program project generally involves the organized efforts of groups of investigators, members of which conduct research projects related to the overall program objective. The grant can provide support for the projects and for certain basic resources shared by individuals in a program where the sharing facilitates the total research effort. Each project supported under a program project grant is expected to contribute to and be directly related to the common theme of the program; the projects under the direction of a principal investigator should demonstrate an essential element of unity and interdependence. This program does not provide support for nonresearch components, such as a clinical referral service, programs in continuing medical education, or programs for demonstration projects and technology transfer.

B. It is planned that awards will be made during fiscal year 1984, to support at least one program project grant depending on the availability of funds. It is anticipated that projects will be initiated September 1, 1984.

C. Proposals should emphasize new ideas and new initiatives and should be concerned with the clinical relevance of new knowledge to the immune system and its disorders deriving from studies in related disciplines.

D. Protocols focused on the study of immune mechanisms in disease should be designed to favor integration and coordination of intra-institutional research projects concerned with immunologic disorders and those in basic biomedical sciences. Programs should include clinical investigative components drawing upon immunologically relevant endeavors in medicine, pediatrics, surgery, pathology, and their subspecialties.

E. While proposals should be based on clinical investigation as the major requirement, the value and place of experimental studies are recognized. Inclusion of basic research components utilizing samples of human source materials in _in vitro_ procedures and those involving laboratory animals serving as feasible models for required in-depth studies are acceptable. Such work, however, should clearly demonstrate relevance to human diseases.

F. Patient oriented studies and those involving _in vitro_ laboratory procedures and the use of experimental animal models should have an immunologic base or draw upon immunologically relevant areas in the disciplines of biochemistry, pharmacology, microbiology, virology, genetics, or pathology.

G. The proposals should consist of a number of demonstrably integrated projects utilizing multifaceted experimental approaches and investigative probes bearing upon either a well defined immunologic disease or upon immune mechanisms common to multiple human disorders.

H. The proposal should clearly explain how the projected multidisciplinary integrated program can be expected to accomplish the stated goal more efficiently and effectively than a series of independent individual grant supported studies.

I. Designation of a program director should be based upon accomplishment, experience as a senior scientist, and ability to assume both leadership of the investigative group and responsibility for scientific, professional, and administrative functions, and commitment devoting a significant amount of his/her time to the project. Each project or subproject in the program should have a designated principal investigator also with a demonstrable record of accomplishment in clinical immunology, immunopathology, or one of the basic science disciplines or clinical specialties relevant to the particular subject of investigation.

J. Thematic approaches involving combined clinical and basic immunologic approaches to the study of autoimmune disorders, congenital and acquired immunodeficiency disorders of children, Acquired Immunodeficiency Disease Syndrome (AIDS), and other related areas are encouraged.

III. MECHANISM OF SUPPORT

Support of a program project in Mechanisms of Immunologic Diseases will be limited to a maximum of five years. If a competing renewal application is planned, it should be submitted only in response to an RFA. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceeding years, and availability of funds. It is recommended that budgetary requests be limited to an approximate total direct cost of $250,000 to $300,000 per annum.

The receipt date for applications will be October 15, 1983. They will undergo initial review in March by the Allergy and Immunology Research Committee and subsequent review by the National Advisory Allergy and Infectious Disease Council in May 1984. September 1, 1984, will be the earliest starting date for successful applicants.

Grant funds may be utilized to support the research activities of scientific and professional personnel, administration, consultation services, central support services, equipment, supplies, travel, and publication costs. Support for research-related costs of patient involvement and medical care may be authorized. Since the program cannot provide funds for new construction, adequate physical facilities must be available for the primary needs of the project. However, moderate alterations or renovations to enhance clinical or laboratory facilities may be allowed if they are necessary to meet objectives of the proposed program.

IV. LETTER OF INTENT

Prospective applicants are encouraged to submit to the Chief, Allergy and Clinical Immunology Branch, NIAID a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institutions. The Institute requests such letters for the purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding, it will not enter into the review of any application subsequently submitted, and is not a necessary requirement for application.

Inquiries should be directed to:

Robert A. Goldstein, M.D., Ph.D.
Chief, Allergy and Clinical
Immunology Branch, IAIDP
National Institute of Allergy
and Infectious Diseases
National Institutes of Health
Westwood Building - Room 755
Bethesda, Maryland 20205
Telephone: (301) 496-7104

V. REVIEW PROCEDURES AND CRITERIA

These are outlined in the NIAID Information Brochure on Program Projects (METHOD OF APPLYING below).

VI. CONSEQUENCES OF LACK OF RESPONSIVENESS TO THE RFA OR OF LATE SUBMISSION

If a letter of intent is submitted, potential applicants will be promptly advised whether or not their proposal is found to be within the research goals and scope of the program as defined in this RFA. Applicants will then have an opportunity to correct deficiencies or weaknesses and to restructure their submissions accordingly. Formal applications that are not responsive to the RFA or are not received by October 15, 1983, will not be accepted for review and will be returned to the applicant.

VII. METHOD OF APPLYING

Before preparing an application, the prospective applicant should request a copy of the NIAID Information Brochure on Program Projects, which contains details of the requirements for multidisciplinary grant applications, from:

Dr. Nirmal Das
Executive Secretary
Allergy, Immunology and Transplantation
Research Committee
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 706
Bethesda, Maryland 20205

Telephone: (301) 496-7966

The Information Brochure contains special instructions for preparing program project grant applications, review procedures and criteria, and other important information.

Use the standard research grant application form PHS 398 (Rev. 5/82). For purposes of identification and processing, the words PROGRAM PROJECT ON MECHANISMS OF IMMUNOLOGIC DISEASES should be typed in item 2 on the face page of the application and a brief covering letter should be attached indicating submission is in response to this NIAID announcement. In addition to following the accompanying format instructions for the development of the application, include expanded material listed below:

A. A brief description of the intended project;

B. A description of available laboratory facilities;

C. Ongoing basic and clinical research relating to immunologic diseases, identifying existing projects and sources of support;

D. Past research by members of the proposed investigative group in basic and clinical immunology;

E. A description of all clinic facilities available for use by the proposed project;

F. Specific information on the institution's present patient load and projections for patient involvement in clinical investigations;

G. The academic positions and major research interests of the program director and his professional staff who will be involved in the work of the program projects;

H. Collaborative possibilities with other area laboratories and investigators and delineation of the roles and manner of anticipated participation and interaction of the principal investigators, consultants, and collaborators.

Application kits may be obtained from the institution's application control office. If not available there, they may be obtained from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 448
Bethesda, Maryland 20205

Forward the complete application to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Please forward a copy (not the original) of the cover letter and the application face page to Dr. Robert A. Goldstein in order to alert NIAID to the submission of the proposal, and to:

Chief, Program and Project Review Branch
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 703
Bethesda, Maryland 20205

ANNOUNCEMENT

STATE SERVICE SYSTEM RESEARCH GRANTS ON THE CHRONICALLY MENTALLY ILL

PUBLIC HEALTH SERVICE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

Application Receipt Date: April 1, 1983

I. BACKGROUND

In 1977, the National Institute of Mental Health (NIMH) initiated the Community Support Program (CSP), a demonstration program to stimulate and assist States and communities in improving services for adults with long-term seriously disabling mental health problems, i.e., the adult chronically mentally ill population.

National goals for the program are:

- to promote development within States and communities of comprehensive community support systems to meet the needs of, increase opportunities for, and improve the quality of life for adults with disabling long-term mental illnesses,
- to promote more effective use of resources to meet the needs of the population of concern,
- to reduce burden on families and communities of coping with major mental disorder and resulting disability,
- to advance the understanding of how most effectively to plan, organize, deliver, monitor, finance, and evaluate treatment, rehabilitation, and support services to chronically mentally ill individuals.

Since the inception of the program, 39 States and the District of Columbia have received NIMH CSP grants to address these goals. Additional States have participated in national and/or regional CSP conferences and other technical assistance initiatives.

In fiscal year 1983, up to $700,000 is available for State service systems research on the chronically mentally ill. Grants will be made for a maximum period of one year. This grant announcement defines activities that can be supported with these funds.

This program is described in the Catalog of Federal Domestic Assistance No. 13.242, Grants for Mental Health Service System Research. Awards will be made under the authority of the Public Health Service Act, 42 U.S.C. 242a and 42 C.F.R., Part 52. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

II. PURPOSE AND OBJECTIVES

The fiscal year 1983 research program recognizes that opportunities and services for chronically mentally ill individuals are shaped, to a large extent, by policy and program decisions at Federal and State levels. Such decisions have to do with legislation, regulations, financing, fiscal incentives and disincentives, organization and staffing of service systems, eligibility for certain levels of care, benefits or service packages, interagency collaboration, and similar factors.

Often these critical decisions are made with limited research knowledge of the costs, consequences, benefits, or other potential effects of alternative approaches.

Research to be supported under this announcement is intended to improve Federal, State, and local planning, policymaking and program management relative to services provided to chronically mentally ill individuals in State mental health and related service delivery systems.

All research projects supported under this announcement must develop generalizable knowledge. Priority will be given to multi-State collaborative projects or to State-specific projects with potential for generalizing to other States.

III. RESEARCH TOPICS

Areas in which research will be supported are:

- Studies on the structure, operation, client outcome, and other effects of State mental health service delivery systems for the chronically mentally ill, including research that compares systems in different States or different locales within States; examines the relation and integration of State mental health, health, and other human services for the chronically mentally ill population; and investigates the impact of such service systems on other components of the broader State mental health service delivery system.

- Studies that assess State mental health and related service delivery systems for particular subgroups of chronically mentally ill clients, such as severely disturbed children and youth, the young adult chronic patient, the homeless chronically mentally ill, and chronically mentally ill individuals in nursing homes and correction settings, or different locales within States and research that assesses innovative service configurations developed by States for serving these subpopulations.

- Studies that examine State service funding and cost issues pertinent to the chronically mentally ill population, including research that compares systems in different States; investigates different funding models and benefit configurations; examines efficiency and cost-effectiveness of services; and investigates resource channeling and coordination for particular subgroups of the chronically mentally ill population.

- Studies on service management and mix in State mental health service delivery systems for the chronically mentally ill, including research that compares systems in different States or different locales within States;

addresses the interaction between service management and continuity of care; and examines the appropriate mix of mental health, health, and other human services for various age, minority, diagnostic, and disability groups within this target population.

IV. ELIGIBILITY

A. State mental health agencies or other appropriate units of State government. (Priority will be given to proposals in which States demonstrate their research capacity and/or research collaboration with university departments and research units.)

B. Regional interstate organizations with experience in mental health service system research and with documented, established links with State mental health agencies.

C. Other public or private, for-profit or nonprofit organizations, such as universities, corporations, etc., in a position to develop collaborative research projects involving single or multiple States (such applicants must provide documented evidence of: established linkages with State mental health and human services agencies responsible for addressing the issue; and willingness of the collaborating State government(s) or other agencies to participate in the projects.)

V. APPLICATION CHARACTERISTICS

Potential applicants are urged to seek pre-application consultation (see page 5). Detailed instructions are included in the application kit. Depending on the specific nature of the project and participating organizations, applications should:

1. Define the issue and discuss its relevance to the overall goal of improving State mental health service delivery systems for chronically mentally ill individuals.

2. Review and document relevant prior and ongoing research.

3. Document the qualifications of the applicant organization and, where appropriate, the collaborating organizations to undertake research on this particular issue.

4. Provide a detailed research plan that includes:

    a. specific goals and objectives of the project,

    b. availability of data relevant to the objectives and the plan for use of currently available data, where appropriate,

    c. research design and, where appropriate, the process for gathering and analyzing data,

    d. plans for reporting project results in a usable form which will encourage intended user group(s) to consider project results in the decision-making process,

e. role(s) of all collaborating organizations, with documentation of their willingness to participate and to assume the intended role(s). (Letters indicating willingness to participate should be included as appendices to the application.)

f. specific management plan for carrying out the collaborative activities in multi-setting or multi-State projects,

g. description of facilities and personnel available, including resumes of key personnel that reflect pertinent research experience, with a clear delineation of specific duties and responsibilities of each,

h. timetable for the accomplishment of the main steps in the project in a one-year period,

i. budget justification.

VI. GENERAL INFORMATION

A. Application

1. Application kits (State applicants use PHS-5161-1; nongovernment applicants use PHS-398 rev. 5/82) may be obtained by contacting:

Grants Operation Section
Parklawn Building - Room 7C-05
5600 Fishers Lane
Rockville, Maryland 20857

B. The original and six copies (two if form PHS-5161-1 is used) of the application should be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

C. State Consultation

1. NIMH staff are available for consultation concerning proposal development in advance of or during the process of preparing an application. Potential applicants should contact NIMH as early as possible for information and guidance in initiating the application process. Inquiries regarding relevance of the proposed project to community Support Program goals should be directed to:

Judith Turner, Chief or
Jacqueline Rosenberg
Research and Evaluation Coordinator
Community Support and Rehabilitation Branch
Division of Mental Health Service Programs
Parklawn Building - Room 11C-22
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4113

2. Inquiries regarding the technical aspects of proposal submission, research design, and methodology should be directed to:

Ronald W. Manderscheid, Ph.D., Acting Chief
Survey and Reports Branch
Division of Biometry and Epidemiology
Parklawn Building - Room 18C-05
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-3343

3. Review and Award

Applications will be reviewed in accord with the usual Public Health Service peer review procedures. They will first be reviewed for technical merit by a review group composed primarily of non-Federal consultants (Initial Review Group) and then by the National Advisory Mental Health Council. Only those applications recommended for approval by the Council will be considered for funding.

Applicants should not expect that site visits will be made.

D. Review Criteria

1. Clarity and specificity of project objectives.

2. Quality of project design and methodology as evidenced by a detailed research plan which includes:

   a. description of the proposed research,

   b. specific aims and rationale for the study,

   c. hypothesis to be tested, if any,

   d. kinds of data expected to be obtained and the means by which the data will be collected, analyzed, and interpreted,

   e. discussion of the limitations of the procedures proposed, if appropriate, in light of the pitfalls that might be encountered, anticipated, and dealth with,

   f. timetable for the accomplishment of the main steps in the project in a one-year period.

3. Significance of the issue(s) and potential of the project for improving State mental health service delivery systems for chronically mentally ill individuals; generalizability of the findings.

4. Appropriateness of the collaborative arrangements to the nature of the problem.

5. Evidence of cooperation and commitment from significant persons and organizations whose support is essential to successful implementation of the project.

6. Potential of the project to foster effective links between university-based researchers and State mental health authorities.

7. Quality of the plan for disseminating results of the project to appropriate audiences in a manner that will facilitate the use of the information.

E. Receipt and Review Schedule

Receipt of Application	Initial Review	National Advisory Mental Health Council	Earliest Award Date
Apr. 1, 1983	May/June 1983	Aug./Sept. 1983	Sept. 1983

F. Award Criteria

1. Quality of the proposed project as determined during the review process.

2. Relationship of the project to the goals and objectives of the NIMH Community Support Program, and likelihood that, if funded, the project will contribute significantly to improving policy-making and/or program management of State mental health service delivery systems for chronically mentally ill individuals.

3. Generalizability of project results to multiple localities or States. (In instances of two projects of similar quality addressing the same issue, priority for funding will be given to a multi-State collaborative project.)

G. Terms and Conditions of Support

1. Support may be requested for one year.

2. Applicants must certify that all applicable Federal regulations will be adhered to. Awards will be administered in accordance with the PHS Grants Policy Statement (rev. 12/1/82).*

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* Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-500-000 (Rev.) December 1, 1982, available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

ANNOUNCEMENT

NEW INVESTIGATOR RESEARCH AWARD (NIRA) IN PREVENTION

PUBLIC HEALTH SERVICE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
NATIONAL INSTITUTE ON DRUG ABUSE
NATIONAL INSTITUTE OF MENTAL HEALTH

January 1983

I. INTRODUCTION

Under the authority of Section 301 of the Public Health Service Act, Section 501 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, as amended, Section 503 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act, as amended, Federal Regulations at 42 CFR Part 52, the three Institutes of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) are seeking applications for New Investigator Research Awards (NIRAs) in Prevention. It is anticipated that approximately six awards will be made in Fiscal Year 1983. Applications must be received by April 1, 1983, to be considered for funding in Fiscal Year 1983.

II. PURPOSE

The NIRA in Prevention is an award to an institution on behalf of a specific individual and is designed to encourage new investigators (or investigators who have established careers in closely related fields and who wish to specialize in prevention research) in the biomedical and behavioral disciplines to develop their research interests and capabilities in prevention research methodology and preventive intervention research in alcohol, drug abuse, and mental health (ADM) fields. The long-range goal of this program is to expand the scientific and clinical knowledge base of prevention theory and thereby produce demonstrable reductions in the incidence of ADM disorders and dysfunctions. To assist in the transition either from training status to that of established investigator or from a related field, this program provides research grant funds for relatively inexperienced investigators (or investigators refocusing their careers) with meritorious research ideas.

III. AREAS OF INTEREST

Prevention research is defined for this Announcement as research focused on, or directly related to, reducing the incidence of: ADM disorders; the high-risk precursors of the disorders; the adverse consequences of high-risk precusors or early manifestations of the disorders themselves. It includes research on (1) primary preventive and health promotion interventions, (2) nonclinical secondary preventive interventions, (3) general population screening methods for early identification, and (4) the role of contributing and inhibiting factors as a basis for development or refinement of preventive intervention strategies.

Applications are particularly encouraged in areas which include but are not limited to:

1. The design, implementation, and evaluation of models of early preventive interventions targeted to individuals/populations at risk for ADM disorders and behavior dysfunctions or who display early signs or precursors thereof. (Interventions should aim to reduce demonstrably both the incidence of a specific disorder or dysfunction and the need/demand for treatment.)

2. Assessment of the differential applicability of preventive interventions for different populations and age groups and the duration of their effects for different demographic, cultural, ethnic, and age segments of the population.

3. Refinement of techniques for differentiating within epidemiologically identified at-risk populations those individuals who are vulnerable for specific ADM disorders and assessment of their receptivity to early preventive intervention.

4. Assessment of the relationship between stressful life events and individual vulnerability and resistance to specific ADM disorders and behavior dysfunctions with the intent of applying these research findings directly to the development of preventive interventions.

5. Development and/or refinement of prevention research and evaluation methods such as instrumentation and measurement techniques, cost-benefit analysis, and community-impact analysis.

IV. ELIGIBILITY

A. Applicant Institutions

All domestic, nonprofit and for-profit organizations and institutions, qualified entities of State and local governments, and eligible Federal institutions may apply.

B. Principal Investigator

This award is restricted to new investigators pursuing a career in prevention research and investigators in closely related fields who are refocusing their careers on prevention research.

For purposes of this announcement, new investigators are defined as those who hold a doctoral degree or its equivalent or have completed formal professional and research training (e.g., someone with an MPH degree and formal research training), have no more than five years of research experience after completion of formal training at the time the award is made, and have not previously been a principal investigator on any PHS-supported research project grant.

Investigators refocusing their careers on prevention research are defined as established investigators with at least five years experience, who have not previously been principal investigators on a National Institute on Alcohol

Abuse and Alcoholism (NIAAA), National Institute on Drug Abuse (NIDA), or National Institute of Mental Health (NIMH) supported research project grant in prevention and who have research training and experience in closely related fields.

C. Concurrent Applications

Submission of an application under this announcement precludes concurrent application for an ADAMHA Research Scientist Development or Research Scientist Award, National Research Service Award, or another NIRA or similar award.

An applicant may apply concurrently for a separate research project grant, provided the time and effort devoted to the research project grant will not conflict or interfere with the time or other commitments of the NIRA.

V. REVIEW CRITERIA

Applications will undergo peer review for scientific and technical merit by Initial Review Groups (IRGs) consisting primarily of non-Federal technical and scientific experts. Particular attention will be given to the following:

1. Adequacy of the principal investigator's research and research-training background as a guide to future development into a creative, independent investigator in the field of ADM-related prevention research.

2. Quality of the individual's past education, scientific training, and potential for a prevention-related research career or letters of reference if research originality and potential are not reflected in past experience.

3. Evaluation of the research proposal for scientific merit, including (a) originality, (b) feasibility, (c) adequacy of the design, (d) plans for analysis and evaluation of data, and (e) overall evidence of the investigator's ability to develop a sound research plan.

4. Adequacy of resources and environment for the successful completion of the proposed research.

VI. SPECIAL TERMS OF THE AWARD

Except as otherwise stated in this announcement, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement.*

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* Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-50-000 GPO-017-020-0090-1 (rev.) December 1, 1982, available for $5.00 from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

salary, title, and staff privileges are determined by the grantee institution in accordance with its established policies for other individuals of the same rank, faculty, or employment status without regard to source of support.

2. Principal investigators must make a significant commitment of time or effort to the research project proposed; while this must be at least 50 percent of full-time activities, a larger commitment is encouraged.

B. Duration

Direct costs may be requested for up to three years of support. Continuation of research support beyond this award may be sought as a regular research grant.

C. Direct Costs

1. The total direct costs requested must not exceed $112,500 for the three-year period; no more than $37,500 may be requested in any one year.

2. An institution may request up to $25,000 plus applicable fringe benefits to support that portion of the principal investigator's salary and benefits which reflects the percentage of time devoted to the NIRA project. The base annual salary from which this amount is derived must be consonant with the policies of the grantee institution governing full-time salary for other individuals of similar rank.

3. Technical support, supplies, publication costs, and limited equipment, as well as necessary travel, may be requested within the direct-cost budget. Requested funds may not be used to supplement a project supported by other funds.

D. Indirect Cost

Indirect costs are allowable in accordance with DHHS policies for research grants.

E. Follow-up Information

To assist in the evaluation of this program, the principal investigators may be requested to provide ADAMHA staff with information about their scientific accomplishments and changes in professional status or institutional affiliation for a period of six years subsequent to termination of the award.

VII. APPLICATION

A. The regular research grant application form PHS 398 (rev. 5/82) must be used in applying for these awards. State and local agencies should use form PHS 5161. Application kits are available in university grants offices or from the following:

Grants Operations Section
Parklawn Building - Room 7C-05
5600 Fishers Lane
Rockville, Maryland 20857

General instructions for applicants are included in the kit.

B. Further information on program requirements and application procedures can be obtained from:

Dr. Ernestine Vandervee
Chief, Psychosocial Research Branch
National Institute on Alcohol Abuse
and Alcoholism
Parklawn Building - Room 14C-17
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4223

Dr. Robert Battjes
Acting Chief, Prevention Research Branch
National Institute on Drug Abuse
Parklawn Building - Room 10A-20
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-1514

Dr. Morton Silverman
Chief, Prevention Reserch Branch
Parklawn Building - Room 11C-06
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4283

C. New Investigator Research Award in Prevention should be typed on line 2 of the face page of the application form.

D. The signed original and six (6) copies of the completed application should be sent to:

Division of Research Grants
National Institutes of Health
5333 Westbard Building
Bethesda, Maryland 20205

E. New investigators should request present or former supervisors to submit letters attesting to their potential for conducting independent research. These should be submitted directly to the Executive Secretary of the review group handling the application. Applicants will be advised of name and address of the Executive Secretary after the application is received.

VIII. RECEIPT AND REVIEW SCHEDULE

Receipt of Application	Initial Review	Advisory Council Review	Earliest Award Date
March 1*	June	September/ October	December **
July 1	October/ November	January/ February	April
November 1	February/ March	May	July

IX. AWARD CRITERIA

Applications recommended for approval by the relevant Institute's National Advisory Council will be considered for funding on the basis of overall scientific and technical merit of the proposal as determined by peer review, program balance, relevant to national need as reflected by each of the ADAMHA Institutes' prevention research priorities, and the availability of funds.

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* April 1, 1983, for first review cycle

** September 1983 for first review cycle

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NIH Guide for Grants and Contracts

Vol. 12, No. 3, March 25, 1983

U.S. DEPARTMENT OF HEALTH
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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

PUBLIC HEALTH SERVICE

In the February 25, 1983 issue of the NIH Guide for Grants and Contracts, a Notice was published indicating that the Public Health Service (PHS) is changing the first Small Business Innovation Research (SBIR) grant application receipt date of March 15, 1983 to May 1, 1983. The receipt was extended to allow eligible small businesses additional time to prepare their grant applications but will still enable the PHS to make SBIR awards in Fiscal Year 1983, that is, before September 30, 1983.

Other changes have also been made in the receipt dates that appear in the PHS Omnibus Solicitation in order to ensure timely processing and review of grant applications for the year beginning October 1, 1983, (Fiscal Year 1984). They are as follows:

- The July 1 and November 1, 1983 receipt dates have been cancelled.
- The two receipt dates for Phase I grant applications for which awards can be made in Fiscal Year 1984 are: October 1, 1983 and February 1, 1984.
- The receipt date for Phase II grant applications for which awards can be made in Fiscal Year 1984 is: April 15, 1984.

The above changes will be reflected in the next printing of the PHS Omnibus Solicitation. Any questions concerning these dates should be directed to:

Ms. Lily O. Engstrom
PHS SBIR Program Coordinator
Office of Extramural Research
and Training
National Institutes of Health
Shannon Building 1 - Room 111
Bethesda, Maryland 20205

Telephone: (301) 496-5356

NOTICE

NATIONAL RESEARCH SERVICE AWARD GUIDELINES REVISED

The Special Edition of the National Research Service Award Guidelines for Individual Awards—Institutional Grants will soon be revised to reflect the change in activation period, the FY 1983 increase in stipend levels, and information pertaining to the involvement of human subjects in training projects. The revision will be published as a Special Edition of this volume (Vol. 12, No. 3, March 25, 1983) of the NIH Guide for Grants and Contracts. Copies will be distributed to institutional offices of sponsored programs and training grant program directors. A limited number of additional copies may be available upon request from the following address:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7441

NOTICE

AVAILABLE NONHUMAN PRIMATES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The National Heart, Lung, and Blood Institute supports a contract program for a resource of nonhuman primates, modelled for atherosclerosis, as well as control animals. The following animals are currently available for sale.

African Green Monkeys
(cercopithecus aethiops)

100 M/F	6 mo. - 6 yrs., domestic born, laboratory reared; 67 of these animals are adapted to an atherosclerotic diet
74 M/F	Adult, wild caught, laboratory housed since 1976; 45 of these animals have been adapted to an atherosclerotic diet

Stumptailed Macaques
(macaca arctoides)

102 M/F	6 mo. - 7 yrs., domestic born, laboratory reared; 90 of these animals have been adapted to an atherosclerotic diet
41 M/F	Adult, wild caught, laboratory housed since 1976; 32 of these animals have been adapted to an atherosclerotic diet

Prices: Negotiable plus shipping and crates. For further information please contact:

Litton Bionetics, Inc.
Kensington, Maryland 20895

Dr. Elizabeth Gard
Telephone: (301) 881-5600, Ext. 268

or

Dr. David Martin
Telephone: (301) 881-5600, Ext. 226

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DCCP-82-18

HEPATITIS B VIRUS AND PRIMARY HEPATOCELLULAR CARCINOMA: BIOLOGICAL INVESTIGATIONS OF VIRUS-HOST INTERACTIONS AND MECHANISMS OF CAUSATION OF HUMAN CANCER

NATIONAL CANCER INSTITUTE

Application Receipt Date: July 15, 1983

The Division of Cancer Cause and Prevention (DCCP) of the National Cancer Institute (NCI) invites grant applications from interested investigators for biological investigations of Hepatitis B Virus host interactions and mechanisms of causation of human cancer.

Grants are awarded to nonprofit and profit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary NIH grant-in-aid, in accordance with PHS policies applicable to Research Project Grants, including cost-sharing. The RFA solicitation, however, represents a single competition, with a specified deadline for receipt of applications. All applications received in response to the RFA will be reviewed by the same National Institutes of Health (NIH) Initial Review Group (IRB) and by the National Cancer Advisory Board. The specific deadline for the receipt of response to the RFA is July 15, 1983. Applications should be prepared and submitted in accordance with the aims and requirements of the following sections:

I BACKGROUND INFORMATION
II OBJECTIVES AND SCOPE
III MECHANISMS OF SUPPORT
IV REVIEW PROCEDURES AND CRITERIA
V METHOD OF APPLYING
VI INQUIRIES

This program is described in the Catalog of Federal Domestic Assistance No. 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended, 42 USC 241, 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

I. BACKGROUND INFORMATION

Of approximately 4 billion people in the world, 210 million are chronic carriers of Hepatitis B virus. This agent is known to cause acute and chronic hepatitis, very probably cirrhosis, and there is very strong epidemiological evidence to indicate that persistent hepatitis B virus infection is associated with subsequent development of primary hepatocellular carcinoma in man. This linkage was discussed at an NCI conference on Hepatitis B virus and Primary Hepatocellular Carcinoma held on May 3 and 4, 1982. Although the role of the virus in the pathogenesis of any of these diseases is not clearly understood, some important phenonenological data has been accumulated, i.e., the long onset period from 20 to 30 years between the onset of persistent infection with the virus and development of liver cancer; the observation that males are more likely than females to develop chronic liver disease and primary hepatocellular carcinoma; and that infants are more likely to develop persistent infection and adults to develop transient infections. The existence of a 210 million chronic carriers of HBV worldwide coupled with recent data which indicates that the lifetime risk of developing liver cancer in these individuals may be approximately 40% indicates that primary hepatocellular carcinoma is a major public health problem worldwide.

Conference participants generally agreed that the NCI should be involved in studies of Hepatitis B Virus and Primary Hepatocellular Carcinoma since this agent was thought to be the best model in humans of a specific viral agent related to a specific cancer. They felt that the epidemiologic evidence linking the two was overwhelming but the basic knowledge of how the virus acts to cause disease or even whether or not it is a transforming agent is completely lacking. Thus both basic and clinically oriented studies should be pursued to gain information on the mechanism(s) by which the virus is causally implicated in the disease and to enable meaningful planning for intervention and prevention of hepatocellular carcinoma in man.

II. OBJECTIVE AND SCOPE

The intent of the RFA would be to encourage research to determine: (a) whether or not hepatitis B virus is a complete carcinogen in humans; (b) the molecular mechanisms underlying the viral transformation of hepatocytes to malignant cells in human and model systems; (c) the characteristics of model systems already developed in terms of their suitability for studying the development of hepatocellular carcinoma and establishing their relevance, if any, to human disease; (d) whether or not any of the gene products of the hepatitis B virus are transforming proteins.

The following representative research is projected: (1) studies to determine whether or not the Hepatitis B Virus is a complete carcinogen in cultured human liver cells or in animal model systems; (2) investigations on the mechanism(s) of oncogenesis of HBV including the role of integrated DNA in transformation, examination of virus coded proteins for transforming potential and development of in vitro model system(s) for transformation; (3) studies on the progression of acute hepatitis through chronic hepatitis to primary hepatocellular carcinoma, including studies on why tumors develop in only a limited number of individuals infected with the Hepatitis B Virus (possible host determinants to the process) and in the mechanism(s) by which chronic infections are maintained in the immunologically competent host; (4) studies on the site of pathology of the disease to shed light on the mechanism(s) of liver damage and carcinogenesis.

III. MECHANISM OF SUPPORT

This RFA will use the traditional National Institutes of Health (NIH) grant-in-aid. The RFA has identified the scope of the Institute's interest. It is expected that responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant. The intent is to fund multiple projects, with total costs amounting to approximately $900,000 for the first year. It is anticipated that awards will be made for a period of up to four years. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit.

IV. REVIEW PROCEDURES AND CRITERIA

A. Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals and fall within one or more of the specified research categories (see II. OBJECTIVES AND SCOPE). If the application is judged by the NCI not to be responsive, the applicant may have it considered as a traditional R01 grant, along with other applications in the next regular review cycle. Should the number of approved grants exceed the dollar set aside for this RFA, those not paid will be considered for funding with other traditional R01 grants in the same funding cycle.

B. The factors considered in evaluating each response to this RFA will be:

1. Scientific merit of research approach, design, and methodology.
2. Research experience and competence of the Principal Investigator and staff to conduct the proposed studies.
3. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.
4. Adequacy of existing/proposed facilities and resources. Applications which specify proposed use of human specimens need to provide assurance and details concerning the nature, source and availability of these specimens to ensure completion of meaningful studies in a reasonable period of time.
5. Scientific, technical or medical significance and originality of proposed research.
6. Reasonableness of proposed costs.

V. METHOD OF APPLYING

A. Format of Application

1. Applications must be submitted on form PHS 398 (Rev. 5/82), the application form for research project grants. Application kits are available at most institution business offices, or may be obtained from the Division of Research Grants (DRG), NIH. The conventional

presentation in form and detail applicable to regular research grant applications should be followed, and the requirements specified under Review Criteria (Section IV above) must be fulfilled.

2. The number and title of this RFA should be typed in section 2 on the front page of the grant application form.

B. Application Procedure

1. The completed original application and six (6) copies should be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

an additional two (2) copies should be sent to:

Dr. John S. Cole, III
Biological Carcinogenesis Branch
Landow Building - Room 9A22
Bethesda, Maryland 20205

Telephone: (301) 496-6085

and one copy of this application should also be sent to:

Dr. Harold Waters
Division of Research Grants
National Institutes of Health
Westwood Building - Room 2A16
Bethesda, Maryland 20205

C. To ensure their review, applications should be received by July 15, 1983. If applications are received after that date, the applicant will have the opportunity of having them considered, along with other unsolicited applications, in the next regular review cycle. The DRG will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VI. INQUIRIES

Inquiries may be directed to Dr. John S. Cole, III, at the above address.

REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

NIH-NCI-DRCCA-OSP-83-2

ADMINISTRATIVE COORDINATING CENTER FOR THE ORGAN SYSTEMS PROGRAM

NATIONAL CANCER INSTITUTE

Application Receipt Date: July 15, 1983

The Division of Resources Centers and Community Activities (DRCCA) of the National Cancer Institute (NCI) invites cooperative agreement applications from institutions capable and interested in establishing a Coordinating Center for the Organ Systems Program. This Request for Applications (RFA) will be utilized to initiate a program in an area of special importance to the National Cancer Program. All applications received in response to this RFA will be reviewed by the same National Institutes of Health (NIH) initial review group. An applicant if funded under this RFA will be supported through the cooperative agreement award in accordance with the policies of the Public Health Service (PHS) and NIH.

The awardee will have the primary responsibility for the planning and direction of the proposed Organ Systems Coordinating Center (OSCC). This will involve active participation and interaction with the NCI Organ Systems Program staff. NCI staff will work closely with the Coordinating Center staff on both administrative and scientific matters. NCI staff will participate with the Coordinating Center staff in the planning of program activities as well as in the annual evaluation of program priorities. NCI staff will periodically review progress to ensure that the Center conforms to the purposes and objectives of the program, as well as conditions of the award. The Board of Scientific Counselors of the DRCCA and the National Cancer Advisory oard will oversee these activities.

An applicant may apply for a project period of up to five years under this RFA. Only one award for an OSCC will be made. The specific amount to be funded will depend on the merit of the applications received and the availability of funds.

It is the intent of this RFA to create an OSCC in a location where a critical mass of resources and qualified cancer administrators and investigators already exists.

The present announcement is for a competition with a deadline for receipt of applications of July 15, 1983. An applicant institution is encouraged to submit a letter of intent and consult with NCI staff before submitting an application in response to this RFA. The letter of intent would be due by April 29, 1983.

This program is described in the Catalog of Federal Domestic Assistance Nos. 13.393, 13.394, 13.395, and 13 396. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended: 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

The successfully funded awardee institution will be required to present its findings and progress to the NCI annually at a specified meeting time. The presentation will include recommendations regarding present and future research pursuits for each organ system. An annual trip to Bethesda, Maryland, should be budgeted for this purpose.

An application for an OSCC should be prepared and submitted in accordance with the aims and requirements described in the following sections:

- I. BACKGROUND INFORMATION
- II. ORGAN SYSTEMS CONCEPT AND GOAL
- III. ORGAN SYSTEMS COORDINATING CENTER
    - A. Organ Systems Working Groups
    - B. Research to be Stimulated by the OSCC
    - C. Communication and Information Transfer
    - D. Criteria and Guidelines for Initiation of a New Organ System Focus and for Possible Termination of an Individual Program
    - E. The Director and Management Structure of the OSCC
    - F. Resources of the Applicant Institution
    - G. Budget, Resources and Data Bases

- IV. ROLE OF THE NATIONAL CANCER INSTITUTE
- V. NATURE OF COOPERATION WITH NCI STAFF
- VI. LETTER OF INTENT
- VII. METHOD OF APPLYING
- VIII. REVIEW PROCEDURES AND CRITERIA
- IX. INQUIRIES

I. BACKGROUND INFORMATION

The program currently in existence is the Organ Systems Program which consists of the former Breast Cancer Program and National Organ Site Program. These are coordinated grants programs of focused research. The Breast Cancer Program, formerly located in the Division of Cancer Biology and Diagnosis, NCI, and now transferred to the DRCCA, has been administered by an NCI staff functioning in close coordination with the Breast Cancer Task Force Committee. This is a multidisciplinary, extramural advisory committee made up of clinical and laboratory research scientists. The National Organ Site Program consists of four grant supported projects of targeted cancer research. Each project is a planned research effort oriented toward cancer at a specific organ site. Currently there are projects concerned with cancers of the large bowel, pancreas, prostate and urinary bladder. The planning, direction and coordination of each project are provided at a headquarters office outside the NCI. Four Project Directors are assisted in planning and administration by the four headquarters staffs and by committees of clinical and laboratory research scientists recruited from institutions throughout the nation.

In May 1982, the National Cancer Advisory Board recommended that the National Organ Site Program be reorganized into an Organ Systems Program with a mission to continue to focus on the large bowel, pancreas, prostate and urinary bladder, and begin to appraise progress in other organ systems in order to identify those which might require specialized attention. In addition, the Breast Cancer Program has been integrated into the Organ Systems Program. A single OSCC external to the NCI will replace the present four headquarters for the large bowel, pancreas, prostate and urinary bladder, and the center will have five Working Groups at the outset: breast, large bowel, pancreas, prostate and urinary bladder. Each Working Group will be responsible for planning, coordination, monitoring, evaluation, and overview of the epidemiologic, laboratory and clinical research components of these programs. Interactions and communication among these components will be fostered through workshops and conferences, and will be maintained through other mechanisms as appropriate. Peer review of research grant applications submitted in response to OSCC Working Group recommendations will be performed as appropriate by initial review groups within the NIH Division of Research Grants (DRG) and NCI Division of Exramural Activities (DEA). The Organ Systems Program will be located within the DRCCA.

II. ORGAN SYSTEMS CONCEPT AND GOAL

This program initiative is being taken because cancers of the breast, large bowel, pancreas, prostate and urinary bladder pose substantial problems in terms of incidence, morbidity, and mortality. Existing research results indicate that there are approaches to these problems, but insufficient exploitation of the leads occurs despite knowledgeable investigators. The NCI and NCAB have considered such criteria and have concluded that there is a need for a targeted organ systems cancer effort. The concept of an OSCC linked with the NCI for complementary programmatic effort is being put forth to address this need. This external organization, the OSCC, will support regular meetings of multidisciplinary Working Groups of scientists in the five respective organ systems areas. These Working Groups will engage in comprehensive program planning identifying the epidemiological, laboratory and clinical research needed to stimulate advancements in these areas. Investigator-initiated, peer-reviewed research projects will be encouraged through program announcements and RFA's to fulfill the program plans.

The goal of the Organ Systems Program is to reduce cancer incidence, morbidity and/or mortality by:

1. Pursuit of targeted research through investigator-initiated efforts.

2. Application of a spectrum of research disciplines to cancer within specific organ systems.

3. Encouragement of accomplished investigators to study cancer in specific organ systems.

4. Encouragement of multidisciplinary collaboration in studying specific organ system cancers.

5. Recruitment of scientific and administrative expertise from the biomedical community for planning and implementing targeted research.

III. ORGAN SYSTEMS COORDINATING CENTER

An applicant institution must present an OSCC program and separate programs for organizing, planning, coordinating, monitoring, and evaluating interdisciplinary activities relating to cancers of the breast, large bowel, pancreas, prostate and urinary bladder.

The following outline describes the basics of an OSCC administrative program and indicates the sequence which should be followed in the application format:

1. Administrative program of the Coordinating Center:

    a. Goals and objectives
    b. Scope of the administrative plan

2. Scientific rationales and activities for each of the five program areas, including how program planning will be carried out, areas of scientific expertise to be involved and how they relate to the activities of the OSCC (the application should not identify individual scientists; they will be specified during the pre-award negotiation according to procedures outlined in section V.A. of this announcement).

3. Scientific rationales and activities for the interaction and coordination of the respective Working Groups.

4. Resources at the Coordinating Center in support of administrative activities:

    a. Scientist administrators and support staff
    b. Size and location of available space
    c. Available resources

An application for the OSCC should provide administrative operational plans and scientific rationales for all proposed activities and will be reviewed with this in mind. The goals and objectives of the OSCC should be consistent with the goals and objectives of the National Cancer Program. The application must include plans for the initial five program areas. The qualifications of the scientist administrators at the OSCC and the organization and management of the OSCC should be presented clearly and succinctly. A description of the available physical space, institutional resources and data management resources at the proposed OSCC should be given.

A. Organ Systems Working Groups:

The planning and direction of scientific efforts for the Organ Systems Program will be provided by five multidisciplinary Working Groups (breast, large bowel, pancreas, prostate and bladder) of expert scientists recruited by the OSCC from institutions throughout the nation. These scientists will be actively engaged in areas of research relevant to the focus of the Working Group. The OSCC will be responsible for managing and coordinating the activities of the Working Groups as appropriate, for continuously evaluating the scientific programs for shifts in emphasis, and for identifying additional organ systems requiring attention. The application should indicate how the OSCC would propose to coordinate the activities of the Working Groups, and how criteria would be developed for initiating new organ system programs and, when necessary, terminating a particular program.

It is anticipated that a portion of the membership of the Working Groups will include members servicing on current NCI Breast, Large Bowel-Pancreatic and Bladder-Prostate committees. This will ensure continuity during the transition. Proposed rotation of Working Group membership should be provided.

A major function of the Working Groups will be to develop detailed program plans for focusing multidisciplinary research in the various organ systems, and to develop new initiatives as appropriate. These plans will be transmitted to the NCI through the OSCC. They will be updated frequently, and formally revised each year. Areas of emphasis will be established with each revision of the plans. The program plans will serve as guides for the kinds of activities needed to maximize the impact of the Organ Systems Program in the areas of prevention, detection, diagnosis, treatment and control.

Proposed RFAs will be submitted to the appropriate NCI Boards of Scientific Counselors. The OSCC and Working Groups with the assistance of NCI staff will publicize these special initiatives through appropriate mechanisms such as OSCC newsletters, NCI program announcements, to encourage investigators to apply for research grants to fulfill the aims and objectives of each program plan. In order to discharge its planning responsibilities, theWorking Groups will be kept informed by NCI staff of all NCI supported research in their respective areas. A description of how each Working Group will monitor research activities should be provided.

B. Research to be Stimulated by the OSCC:

Work to be stimulated by the OSCC Working Groups through mechanisms described in section III.A. above will include epidemiological, laboratory and clinical research in cause and prevention, detection, diagnosis, pre-treatment evaluation, and treatment. The emphasis will be programmatic and multidisciplinary, not restricted by conventional categorical approaches. Basic research clearly focused on cancer of a specific organ system will be addressed if it is relevant to a program plan. Each Working Group will monitor and evaluate all organ systems research as part of its program planning and coordination activities.

C. Communication and Information Transfer:

The OSCC Working Groups will be responsible for state-of-the-art assessments for each of the organ systems involved. To meet this end, and to discharge their planning responsibilities, the Working Groups will conduct workshops and conferences on a timely basis to discuss areas deemed ready for research implementation, and will survey relevant fields and make appropriate recommendations. Such workshops and conferences would normally result in written communications for the scientific and medical professions, and might identify areas with potential for medical applications. These are examples of types of communication activities which the OSCC would undertake, and are not meant to be all inclusive.

D. Criteria and Guidelines for Initiation of a New Organ System Focus and for Possible Termination of an Individual Program:

The OSCC will develop criteria and guidelines for the possible initiation of a new Organ System Program, for the operation of the existent Programs, and for the possible termination, when necessary, of an individual Program. These criteria and guidelines will be subject to the review by the NCI, the DRCCA Board of Scientific Counselors and the National Cancer Advisory Board. As an example, this application should set forth what criteria and guidelines the OSCC would follow in designing a new Organ System Program for upper respiratory tract, and how such a new program would be established, phased in, and coordinated with the overall Organ Systems Program. (This specific example is intended to be illustrative and does not imply any commitment or preference by the NCI).

E. The Director and Management Structure of the OSCC:

The proposed Director of the OSCC should be a health professional with demonstrated competence in cancer research, and in cancer research administration. The Director will have recognized strong interest in, and professional identification with the cancer field. The Director, in collaboration with NCI staff and advised by the Working Groups, will be responsible for setting objectives and developing strategies for carrying out the Organ Systems Program. The Director also will be responsible for the day-to-day operation and administration of the Coordinating Center. The Director must make a significant commitment of effort to the OSCC. The general duties responsibilities and authority of the OSCC Director should be fully described. A description of the management structure and operating procedures for the OSCC and the Working Groups should be provided; mechanisms for communication, collaboration, and multidisciplinary input into the OSCC should be described. The OSCC should be organized around a core of highly competent scientist administrators. This should include an individual with a program planning background. Key personnel should have demonstrated capability for obtaining peer reviewed project support. These scientist administrators will be comprised of the Director of the Coordinating Center and the additional administrator(s) needed to achieve the goals of the OSCC. A detailed justification for the proposed core of scientist administrators must be presented by the applicant institution. This should include each administrator's qualifications, scientific contributions, level and type of effort which the administrator will contribute to the OSCC, and level of support requested. Curriculum vitae should be provided on all key professional and other staff; relevant publications should be cited.

F. Resources of the Applicant Institution:

The institutional setting of the OSCC should be described, including the institutional commitments in support of the OSCC, personnel available with appropriate expertise, and the relationship of the OSCC to the institutional and departmental structure.

The physical location of the OSCC, square feet of space available, and all resources in support of the OSCC should be described. It is desirable for an applicant institution to have a record of cancer research achievement and to have currently established programs of substantial cancer research supported by funds obtained through competitive national peer review. The current administrative activities at the applicant institution which are relevant to the proposed OSCC administrative plan should also be described, as well as how these would relate to the proposed OSCC.

G. Budget, Resources and Data Bases:

A detailed budget with time and effort for OSCC scientist administrators and support personnel should be included and justified. The number of consultants required, travel required, and general supplies for the OSCC as well as support for the operation and management of the Working Groups should be fully described and justified. Support for Working Groups may be subcontracted as needed. A brief description of each resource should be provided, explaining its significance in support of the program activities, the proposed users, and the total personnel and other costs. The budget should justify each resource within the OSCC. Resources include any equipment, facility, or material which supports the entire administrative program of the OSCC or which is used by administrators within the OSCC. Information should be provided on the capability of an applicant institution to utilize existing data bases at the NIH or elsewhere in each of the five organ systems areas. Details shoul be provided on plans for developing additional data relevant to the areas to be studied, and on the resources for storing and analyzing these data at the OSCC.

IV. ROLE OF THE NATIONAL CANCER INSTITUTE

The Director of the NCI is ultimately responsible for the Organ Systems Program and fulfills this responsibility through the Director, DRCCA. and Organ Systems Program Branch, DRCCA. NCI Program Directors within the Organ Systems Program Branch will provide liaison and guidance, and will participate in planning, organizing and administering the Organ Systems Program. They will provide liaison between the OSCC Director, the Working Groups, and the NCI. They assure that the Organ Systems Program will function within the framework of policies and regulations which govern all NIH extramural programs. They will be available to the OSCC Director and the Working Groups for consultation, and they can be expected to coordinate the Organ Systems Program with other NCI programs. To provide this liaison, NCI Program Directors will participate in the activities of the Working Groups, in the workshops of the Organ Systems Program, and in meetings and workshops of related programs of other Divisions of the NCI and NIH.

Annual progress reports will be submitted by the OSCC to the Organ Systems Program Branch and will be reviewed by the DRCCA Board of Scientific Counselors. At appropriate intervals, progress will be reviewed by the Director, NCI, the NCAB and President's Cancer Panel. Report format will be provided by DRCCA staff.

V. NATURE OF COOPERATION WITH NCI STAFF

A. Membership of Working Groups:

It will be the responsibility of the OSCC to form the membership of the Working Groups subject to NCI approval. Each group will include a member from the NCI Organ Systems Program Branch. Membership rosters will be submitted by the OSCC for approval by the Chief, Organ Systems Program

Branch. If any part of the membership is unacceptable to the NCI, the specific reasons for lack of approval will be communicated to the OSCC within 15 working days after receipt of the membership rosters. NCI staff will work with the OSCC to resolve any differences. If these differences cannot be resolved, they will be submitted to an arbitration panel appointed by the Director, DRCCA, NCI, with concurrence by the OSCC. This appeals process in no way affects the right of the OSCC to subsequently appeal an adverse determination using the NIH informal appeals system and the formal Department of Health and Human Services procedures.

B. Quality Control:

NCI staff will review, monitor and assess the mechanisms and procedures developed to carry out the objectives of the OSCC.

C. Scientific Resources:

NCI staff will serve as a resource for information on pertinent intramural and extramural NCI funded activities. This staff will assist the Working Groups in gathering and coordinating information for their planning activities.

D. Data Management:

NCI staff will have access to all data available at the OSCC and will periodically review data management by the OSCC. Data must be available for external monitoring if required by the NCI.

E. Reporting Requirements:

It will be the responsibility of the applicant to develop the details of a process by which the OSCC will report and record the activities of the Working Groups. An annual progress report of the OSCC will be submitted to the NCI, Organ Systems Program Branch. A report format will be provided. Following receipt of the report, progress will be reviewed by NCI staff and the DRCCA Board of Scientific Counselors.

VI. LETTER OF INTENT

A letter of intent may precede the submission of a cooperative agreement application, and would be due by April 29, 1983. This should be suitable for review for responsiveness to this RFA. All such letters will be answered by NCI staff within ten working days.

VII. METHOD OF APPLYING

Institutions within the United States may apply. Complete applications are due before close-of-business July 15, 1983, and must address all requirements as represented in this RFA. An application should be submitted on Form PHS-398 (Revised 5/80), which is the application for the traditional research project grant and is available in the business or grant contracts offices at most academic and research institutions, or from the DRG, NIH, Bethesda, Maryland 20205. There are no page limitations; however, applications should be as concise as possible. The words Organ Systems Coordinating Center should be typed in bold letters on line number two of the face page of the application and also on the outside of the mailing package. Additionally, a brief covering letter should accompany the application indicating that it is being submitted in response to this RFA. The original and six copies of the application should be submitted to the DRG, NIH, as directed in the grant application instruction.

An additional copy should be sent to:

Referral Officer, Grants Review Branch
Division of Extramural Activities
National Cancer Institute
Westwood Building - Room 826
5333 Westbard Avenue
Bethesda, Maryland 20205

Two additional copies should also be sent to:

Chief, Organ Systems Program Branch
Division of Resources Centers and
Community Activities
National Cancer Institute
Blair Building - Room 3A05
8300 Colesville Road
Silver Spring, Maryland 20910

VIII. REVIEW PROCEDURES AND CRITERIA

Applications responding to this RFA will be reviewed by an appropriate initial review group of the NIH. Final review will be provided by the National Cancer Advisory Board.

Reviewers will consider the application in terms of the capability to implement the operations and activities described in sections III.A. through III.G. above. Attention will be directed toward:

1. Proposed programmatic activities including planning capabilities;
2. Scientific rationales and administrative plans for implementing and managing the proposed programmatic activities;
3. Disciplinary composition of the Working Groups with respect to balance and breadth of types of expertise, (individual scientists are not to be identified);
4. Resources of the applicant institution;
5. Qualifications and experience of the proposed OSCC Director as related to ability to organize, manage and direct an OSCC;
6. Qualifications, experience, proposed duties and responsibilities of other professional and support personnel.

IX. INQUIRIES

Inquiries related to further information, application development or letter of intent should be directed to:

Andrew Chiarodo, Ph.D.
Chief, Organ Systems Program Branch
Division of Resources Centers and
Community Activities
National Cancer Institute
Blair Building - Room 3A05
8300 Colesville Road
Silver Spring, Maryland 20910

Telephone: (301) 427-8818

ORGAN SYSTEMS COORDINATING CENTER

TIMETABLE

March 25, 1983	-	Formal Release of the Request for Application
April 29, 1983	-	Receipt of letters of intent
July 15, 1983	-	Due date for applications
September-November 1983	-	Review of applications
January 1984	-	Review of applications by the National Cancer Advisory Board
March 1, 1984	-	Initial Award

ANNOUNCEMENT

NON-INVASIVE APPROACH FOR DETECTION OF LUNG CANCER

NATIONAL CANCER INSTITUTE

The Diagnosis Branch of the National Cancer Institute (NCI) is inviting grant applications from interested investigators for pilot studies involving the use of gas chromatographic-mass spectrometric techniques for the chemical analysis of the volatile organic components of human expired air in an attempt to identify and quantitate characteristic constituents associated with lung cancer which may have potential for early diagnosis of this malignancy. Profiles or patterns from lung cancer patients should be distinguished from those of patients with pulmonary granuloma, pneumonia, chronic bronchitis, bronchiectasis, emphysema and other associated pulmonary diseases. The technology is available and capable of automation if pilot studies should suggest that larger studies would be worthwhile. This could provide a non-invasive method for the identification of persons at high risk and those with early pulmonary tumors who would benefit from further diagnostic tests.

I. BACKGROUND

Lung cancer mortality has increased continuously over the last half century. The high mortality is felt by many to be due to late diagnosis. Because current screening methods by sputum cytology and chest radiography, individually or in combination, do not provide convincing evidence that this dilemma can soon be resolved, other approaches to detection must be sought. Findings from studies in physiological chemistry show that the composition of expired air in health reflects amounts of all volatile constituents in the blood, and that in disease it would include those compounds which are intimately associated with pathologic processes. Hence, volatile expired constituents offer a potential source of quantitative information not only of the disease processes but may also serve as chemical signals for early detection and diagnosis of disease states of the body. Preliminary data is already available on normal profiles for correlation with the disease state. Other studies have documented the significance of this technique in detecting chemical exposure. These proposed studies would be a first step in evaluating volatile components in expired air to assess their value in the diagnosis of lung cancer. Lung cancer patients would be compared with benign lung disease patients and healthy matched controls. The study would also look for correlations between the magnitude of any marker compounds and the estimate of tumor burden.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.394, Cancer Detection and Diagnosis Research. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended: 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

II. APPLICATION AND REVIEW PROCEDURES

Applications should be submitted on Form PHS-398 which is available at most institutional business offices or from the Division of Research Grants (DRG), National Institutes of Health (NIH). There are three receipt dates each year for new applications: March 1, July 1, and November 1. Review and award of the successful applications will be in accordance with the usual NIH procedures governing research grants. Funding decisions will be based upon scientific merit, program relevance and the Institute's ability to fund.

The title of this Program Announcement should be typed in Section 2 on the front page of the grant application form. The original and six copies of the application should be sent or delivered to:

Applications Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

In order to alert the Diagnosis Program to the submission of proposals as requested above, copies of the face page and summary page of such applications should be forwarded under separate cover to:

K. Robert McIntire, M.D.
Chief, Diagnosis Branch
Program Director, Diagnosis Program
Division of Cancer Biology and Diagnosis
National Cancer Institute
Bethesda, Maryland 20205

Telephone: (301) 496-1591

Additional information regarding the program may be obtained by contacting Dr. McIntire.

ANNOUNCEMENT

SPECIFIC IMMUNOASSAYS FOR CANCER ASSOCIATED ISOENZYMES

NATIONAL CANCER INSTITUTE

The Diagnosis Branch of the National Cancer Institute (NCI) is encouraging submission of individual research grant applications for studies involving the development of sensitive quantitative assays using monoclonal antibodies which could accurately identify and monitor levels of various isoenzymes that have been shown to be quantitatively increased in certain cancers. The objective of this research would be to determine the value of analyzing isoenzymes levels in the serum as potential diagnostic and prognostic tumor markers. Efforts should be made to relate specific isoenzymes to given tumor types and demonstrate a correlation with changes in tumor mass.

I. BACKGROUND

A large number of isoenzymes have been linked with human cancer. However, there are many inconsistencies in the data, some of which may be due to variations in the specificities and cross-reactivities of the antibodies, others to problems in detecting low but still abnormal levels in serum by classical electrophoretic and staining techniques. In addition, some of the isoenzyme forms in tumor extracts have similar charges, hence, cannot be easily distinguished by electrophoresis alone. Monoclonal antibodies directed against the individual forms should help distinguish them.

Some isoenzymes which are known to have structural differences, have not been distinguished by classical immunological techniques using xenogeneic antisera. Monoclonal antibodies could have the necessary specificity to distinguish these forms, allowing the cancer associated isoenzyme to be used as a tumor marker. Minor changes unnoticed by earlier techniques might indicate antigenic forms of the enzyme specific for a particular tumor.

There is a need for developing antibodies that recognize isoenzymes with great specificity and are not dependent upon functional activity or physicochemical properties of the enzyme for that specificity. Monoclonal antibodies have become very powerful new tools in biology and medicine since the "hybridoma" technique was first described by Kohler and Milstein. The development of these antibodies would provide the technology for the production of antisera with the built-in ability to insure reproducibility of results for unlimited numbers of tests. The hybridoma technique is widely used for detection of tumor-related surface antigens. However,

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This program is described in the Catalog of Federal Domestic Assistance, No. 13.394, Cancer Detection and Diagnosis Research. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

little is being done to exploit its potential use in identification and quantitation of cancer associated isoenzymes. This announcement is a step in stimulating research in this direction.

II. APPLICATION AND REVIEW PROCEDURES

Applications should be submitted on Form PHS-398 which is available at most institutional business offices or from the Division of Research Grants (DRG), National Institutes of Health (NIH). There are three receipt dates each year for new applications: March 1, July 1, and November 1. Review and award of the successful applications will be in accordance with the usual NIH procedures governing research grants. Funding decisions will be based upon scientific merit, program relevance and the Institute's ability to fund.

The title of this Program Announcement should be typed in Section 2 on the front page of the grant application form. The original and six copies of the application should be sent or delivered to:

Applications Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

In order to alert the Diagnosis Program to the submission of proposals as requested above, copies of the face page and summary page of such applications should be forwarded under separate cover to:

K. Robert McIntire, M.D.
Chief, Diagnosis Branch
Program Director, Diagnosis Program
Division of Cancer Biology and Diagnosis
National Cancer Institute
Bethesda, Maryland 20205

Telephone: (301) 496-1591

Additional information regarding the program may be obtained by contacting Dr. McIntire.

ANNOUNCEMENT

MINORITY HYPERTENSION RESEARCH DEVELOPMENT SUMMER PROGRAM

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: September 15, 1983

The Division of Heart and Vascular Diseases (DHVD) of the National Heart, Lung, and Blood Institute (NHLBI) is accepting new and competing renewal applications for Institutional National Research Service Awards for research training under the Minority Hypertension Research Development Summer Program.

The Minority Hypertension Research Development Summer Program is intended to (1) encourage the recruitment and development of minority investigators in specialized areas of research, prevention, control and education related to hypertension and (2) stimulate hypertension research, prevention, control and education by offering minority school faculty members and graduate students the opportunity to enhance their research capabilities in these areas.

Training will be offered through hypertension training centers which have well-established hypertension research and training programs and are within 100 miles of (a) minority school(s) or provide satisfactory alternative arrangements for communication and exchange. The centers will collaborate with minority schools to work out plans for the identification, selection and development of participating minority school faculty members or graduate students.

Minority schools are those in which a majority or significant proportion of its enrollment is comprised of students of minority ethnic groups including, but not limited to Blacks, Spanish-speaking Americans, Native Americans, Pacific Islanders and Asian Americans, and which have a demonstrated commitment to the special encouragement of minority faculty, students, and investigators. The minority school must commit itself to encouraging appropriate faculty members or graduate students to participate in this program, to continue the faculty members or graduate students in status after the summer session(s) and guarantee at least limited resources for his or her hypertension research and teaching activities.

Participating faculty members or graduate students must be nominated by the minority school, be accepted by the Training Center, and agree to report annually for six years after training on his or her academic status, publications, grants and/or contracts and teaching activities related to hypertension.

This program is described in the Catalog of Federal Domestic Assistance Nos. 13.397, Heartt and Vascular Diseases Research. Awards will be made under the authority of Public Health Service Act, Section 472, 42 USC-2891-1 and administered under PHS grants policy and Federal Regulation 42 CFR Part 66. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

Applications may request funds to provide stipends for the duration of a summer program of $1,170-$1,643 per month for minority school faculty member participants and $441 per month for minority school graduate student participants. In addition, funds may be requested for trainee travel; tuition and fees essential to the training; health insurance coverage for participants during the summer session; and up to $1,250 per faculty member and $750 per graduate student for institutional allowances which includes personnel, supplies, equipment essential to the program, and consultant costs when specifically justified. Indirect cost allowances will be limited to 8 percent of the total allowable direct costs or the actual rate, whichever is lower. These budget items are subject to administrative revision.

The present announcement is for a single competition with a September 15, 1983 receipt date for applications. These applications will be reviewed at the February 1984 meeting of the National Heart, Lung, and Blood Advisory Council. Awards will be made beginning May 1, 1984. Applications not received by September 15, 1983, will be returned to the applicant. Guidelines for the development of the application may be obtained by contacting Dr. George A. Hayden at (301) 496-1724.

LETTER OF INTENT

Prospective training center applicants are asked to submit a letter of intent not later than May15, 1983 to:

Dr. George A. Hayden
Research Training and Development Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A-08
Bethesda, Maryland 20205

The Institute requests such letters to obtain an indication of the number and the scope of applications which will require merit review. A letter of intent is not binding and will not enter into the review of any proposal subsequently submitted. The letter should briefly describe the composition of the Hypertension Training Center, participating Minority Institutions, the overall approach, and areas of interest for the Minority Hypertension Research Development Summer Program.

ANNOUNCEMENT

THE NCI CLINICAL INVESTIGATOR AWARD

NATIONAL CANCER INSTITUTE

Application Receipt Dates: June 1, October 1, February 1

I. SUMMARY AND PURPOSE

The National Cancer Institute (NCI) announces the availability of Clinical Investigator Awards for the purpose of developing physician-researchers in basic and applied cancer sciences. The initiation of this award is intended to encourage recently-trained highly-qualified physicians (M.D. or D.O.) to undertake careers in cancer research. The award is prompted by the chronic shortage of physician-investigators particularly surgical oncologists, radiation oncologists, preventive oncologists, physiatrists, nutritionists and epidemiologists. It is expected to facilitate the awardees' transition to independent basic or applied researcher. The award will enable successful candidates to investigate for up to three years a defined cancer problem under the guidance of an active researcher who has the knowledge, background and research experience required to be a mentor in that field.

II. ELIGIBILITY

A. Candidate

Applications may be made by institutions on behalf of candidates who hold the M.D. or D.O. degrees. Those who hold a Ph.D. or comparable research degree, either with or without an accompanying M.D. or D.O. are not eligible for the Clinical Investigator Award. Nor are candidates who are or have been principal investigators on PHS supported research grants, program projects or new investigator awards. Candidates should have at least two years of clinical training at the postdoctoral level by the projected start of the award, but should not have more than seven years postdoctoral experience at the time of application for the award. In exceptional circumstances, people having less than two, or more than seven, years' postdoctoral experience may qualify for the award. However, the applicant must provide a very powerful justification for such an exception. Candidates must provide evidence of a serious intent to enter upon an academic research career.

Only United States citizens, nationals or permanent residents may be presented as candidates for this award.

This program is described in the Catalog of Federal Domestic Assistance No. 13.398, Cancer Research Manpower. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

B. Institution

The sponsoring institution must have a strong, well-estblished research program in the candidate's area of interest, and experienced faculty members in the clinical and basic departments relevant to the candidate's proposed training. The institution must include a plan for the candidate's research and academic development. Only domestic institutions are eligible.

C. Preceptor

The candidate's primary preceptor must be a competent investigator in the area of the candidate's proposed research activity. The preceptor must be active currently as an investigator, and must be prepared to provide personally much of the candidate's research supervision. The award is intended to provide an intensive, supervised research experience for the successful candidate.

III. PROVISIONS OF THE AWARD

The Clinical Investigator Award is made for a maximum nonrenewable and nontransferable period of three years. Support is based upon a full-time, twelve-month staff appointment. The award will provide salary support not to exceed $30,000 annually from NCI funds for the three-year period. The actual salary must be consistent with the established salary structure of the grantee institution for persons of equivalent qualifications, experience, and rank. Up to a total of $10,000 annually will be provided for supplies, equipment, travel, etc., which are necessary for pursuit of the awardee's research program. Funds will be provided for the reimbursement of indirect costs at a rate not to exceed eight percent of the total allowable direct costs. When requested, the grantee institution's share of the fringe benefits may be paid as a direct cost (if not treated as an indirect cost) on that portion of the employee's salary provided by the NCI Clinical Investigator Award.

It is expected that the candidate will spend at least 75 percent of his/her time in research during the period, with the remainder being divided among other activities such as teaching, pertinent clinical training, research training, and academic studies. An appropriate sponsor must assume responsibility and provide guidance for the research development in the chosen areas.

Institutions may apply for awards on behalf of named individuals meeting the above criteria. It is not essential for the applicant institution to commit itself in the application to eventual placement of the candidate on its permanent, full-time faculty, but it is expected that institutions will choose candidates who will be able to meet the criteria for making that decision. Evidence of the commitment of the institution to the candidate's research development must be provided.

Candidates for this award may not concurrently apply for a Research Career Development Award, an Academic Award or a New Investigator Research Award.

Candidates must be nominated by an institution on the basis of qualifications, interests accomplishments, motivation and potential for an academic or research career. Candidates must have one or more sponsors at the institution who are recognized as accomplished researchers or teachers in the candidate's area of proposed development. The sponsor(s) must provide (1) his/her concept of a development and research plan for the candidates; (2) his/her updated curriculum vitae with a complete bibliography and research support; and (3) a letter indicating willingness to provide guidance and support for the award's duration.

Candidates must provide a full description of the proposed research and career development plan for the three-year period of the award. The candidate must be prepared to commit full-time effort to the objectives of this award.

Candidates must agree to inform the NCI annually for a period of ten years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

IV. REVIEW CRITERIA

Applications for the NCI Clinical Investigator Award receive initial technical merit review by an NCI review committee and secondary review by the National Cancer Advisory Board.

Criteria for review include:

A. The candidate's potential for a career in independent research;

B. The candidate's commitment to a research career;

C. The overall merit of the candidate's three-year plan for research and the development of research skills;

D. The quality of the candidate's clinical training and experience;

E. The institution's ability to provide quality facilities, resources, and opportunities necessary to the candidate's research development as indicated in the application;

F. The quality of the faculty in the departments relative to the area of study;

G. The ability and plans of the sponsor or sponsors who will guide the candidate in his career development;

H. The candidate's conformance to the eligibility requirements discussed earlier.

V. HOW TO APPLY

An application for this award should be made on form PHS 398 (Rev. 5/82). Application receipt dates are: February 1, June 1, and October 1. At the time the required number of applications are submitted to the NIH Division of Research Grants as indicated in the instructions in the application kit, please send a copy to:

Barney C. Lepovetsky, Ph.D., J.D.
Chief, Cancer Training Branch
Division of Resources, Centers,
and Community Activities
Blair Building - Room 717
8300 Colesville Road
Silver Spring, Maryland 20910

Telephone: (301) 427-8898

ANNOUNCEMENT

U.S. PUBLIC HEALTH SERVICE HEALTH SCIENTIST EXCHANGES

HUNGARY, POLAND, ROMANIA, USSR, YUGOSLAVIA

FOGARTY INTERNATIONAL CENTER

In accordance with separate agreements between the Government of the United States and the Governments of Hungary, Poland, Romania, USSR, and Yugoslavia, programs for the exchange of health scientists have been established and are jointly supported. The programs are administered on behalf of the Public Health Service (PHS) by the Fogarty International Center (FIC) of the National Institutes of Health (NIH).

I. PURPOSE

The intent of the health scientist exchange programs is to foster collaborative activities between well-qualified health professionals and biomedical scientists in the U.S. and participating countries in the study of health and biomedical problems that are of mutual interest and that lend themselves to a cooperative approach. Under the programs, a limited number of individuals from each country are supported for varying periods of work in the other country. Activities may include the sharing of consultative and technical advice on individually conducted research in either country or joint research between collaborating scientists. Priority will be given to those whose work in the host country will have a good prospect for opening future and continuing collaborative ties; will strengthen and expand ongoing collaborative relationships; or will have particular and immediate benefits to both the United States and the participating country.

The programs do not provide support for formal, academic, clinical or research training, or for the primary purpose of attendance at scientific meetings.

II. ELIGIBILITY

U.S. applicants for the programs must meet the following basic requirements:

- be U.S. citizens or permanent U.S. residents,
- hold an advanced degree (normally a doctorate) in one of the health sciences or related fields,
- have professional experience in the health or biomedical fields appropriate to the proposed study,
- be affiliated with a U.S. public or private nonprofit educational, research, or clinical institution.

Working knowledge of the host country language is highly desirable. Prospective long-term participants are urged to study the language intensively in preparation for their visits.

III. SUPPORT

A. Hungary, Poland, Romania, USSR

Under the agreements with Hungary, Poland, Romania and the USSR, the sending side pays for all international transportation costs to the port of entry; the receiving side pays for laboratory costs, in-country travel, and a living allowance. For U.S. participants the following pertain:

- Travel. The Fogarty International Center will provide round trip jet economy class fare for the participant between U.S. home city and the host city abroad. Travel will be in accordance with U.S. Government travel regulations, which require maximum use, where available, of U.S. air carriers. Additional costs of indirect routing at the option of the participant must be at his or her personal expense. An allowance for 22 pounds or unit of excess accompanied baggage will be included for long-term visits. A travel allowance for accompanying family members cannot be provided.

- Living Allowance. The host government will pay for lodging and provide a daily living allowance and in-country travel.

- Health Insurance. The host government will provide the participants with comprehensive health care for accidents and unanticipated medical needs during their stay in the host country. Visitors to Hungary, Romania and the USSR must arrange coverage for any accompanying family members. The Polish Ministry of Health and Social Welfare will provide health insurance coverage for accompanying family members.

B. Yugoslavia

The U.S.-Yugoslav Joint Board will provide round trip, jet economy class fare for the participants between the U.S. home city and the Yugoslav host city. A travel allowance for any accompanying family members cannot be provided. The cost of lodging, a daily living allowance, and other necessary local program-related expenses as well as health insurance coverage for the participant will also be paid for by the Joint Board.

IV. DURATION AND PRIOR CONTACTS

Periods of participation are expected to be no less than two weeks and generally no longer than 12 weeks, although variations from these periods will be considered where necessary and justified. If the applicant has had prior contact with proposed host(s), which is highly desirable, evidence of such contact should be submitted with the application.

V. APPLICATION AND SELECTION

Application materials, containing detailed information for U.S. health professionals interested in participation, will be provided on request by the FIC at the address given below. In addition to biodata and other supporting documentation, the applicant will be required to include a summary description of the proposed activity to be carried out.

After initial technical review, final selection of U.S. participants from among applicants is made by a review committee of the U.S. PHS with the concurrence of the host country and in accordance with the number of participants agreed to and funding availability. Notification of selection decisions is made to U.S. participants by the FIC. Applications will be received on a continuing basis. The review and selection process will take approximately six months.

VI. REPORTS AND PUBLICATIONS

U.S. participants must submit a summary report of work accomplished to the FIC following their visit. Technical articles may be submitted to scientific publications without prior clearance of the NIH or host country authorities. However, the support of the program should be acknowledged.

VII. INQUIRIES AND APPLICATION MATERIALS

For U.S. applicants:

Program Officer
U.S.-Eastern European Health Scientist Exchanges
International Coordination and Liaison Branch
Fogarty International Center
Building 38A - Room 614
National Institutes of Health
Bethesda, Maryland 20205

Eastern European and Yugoslav scientists interested in participating in these programs should apply to their respective Ministries of Health.

ANNOUNCEMENT

BIOMEDICAL RESEARCH FELLOWSHIP OPPORTUNITIES ABROAD

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) of the National Institutes of Health (NIH) announces the availability of postdoctoral fellowships to U.S. health scientists who wish to conduct collaborative research abroad. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical, behavioral and health sciences.

Programs Available to U.S. Citizens or Permanent U.S. Residents

ALEXANDER VON HUMBOLDT FOUNDATION POSTDOCTORAL RESEARCH FELLOWSHIPS
(Supported by the Federal Republic of Germany)

FRENCH NATIONAL INSTITUTE OF HEALTH AND MEDICAL RESEARCH POSTDOCTORAL FELLOWSHIPS
(Supported by the Government of France)

NIH-FRENCH NATIONAL CENTER FOR SCIENTIFIC RESEARCH EXCHANGE PROGRAM
(Jointly Supported by the Governments of France and the United States)

SENIOR INTERNATIONAL FELLOWSHIPS
(Supported and administered by the FIC)

SWEDISH MEDICAL RESEARCH COUNCIL FELLOWSHIPS
(Supported by the Government of Sweden)

SWISS NATIONAL SCIENCE FOUNDATION POSTDOCTORAL FELLOWSHIPS
(Supported by the Government of Switzerland)

The eligibility requirements of each program vary and this information is provided in each program's brochure which is available upon request. However, at a minimum, each candidate must have an earned doctoral degree in one of the behavioral, biomedical or health sciences and some postdoctoral experience.

The receipt date for applications to the FIC Senior International Fellowship Program is June 1, 1983. The receipt date for all other applications except those to the Alexander von Humboldt Foundation is October 1, 1983. Applications for the Alexander von Humboldt Foundation Postdoctoral Research Fellowships are available and are accepted throughout the year. For those fellowship programs with an October 1 receipt date, application kits will be available from April 1, 1983 to September 15, 1983. The organization that provides financial support for each of the programs selects candidates for participation. While the maximum period of support for all programs is one year, the minimum period of support varies with each program.

Prospective applicants for Senior International Fellowships, the FIC sponsored program, may obtain information brochures from the above address. However, application kits for Senior International Fellowships may be requested only through the applicant's dean or equivalent institutional official any time between January 15 and May 15, 1983.

All correspondence should refer clearly to the specific program of interest. For further information, please send a self-addressed label with your request to:

International Research and Awards Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

*U.S. GOVERNMENT PRINTING OFFICE : 1983 O-381-144/301

NIH Guide
for Grants and Contracts

Vol. 12, No. 4, April 22, 1983

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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National Institutes of Health

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(Continued)

The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

REQUEST FOR NOMINATIONS OF INDIVIDUALS FROM SMALL BUSINESS ORGANIZATIONS TO SERVE AS MEMBERS OF NIH SCIENTIFIC REVIEW GROUPS FOR THE SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

The National Institutes of Health (NIH) invites nominations of individuals representing small business organizations for membership on its scientific peer review groups. These groups provide the technical and scientific merit review of Small Business Innovation Research grant applications. Scientists serving on these groups advise the NIH on the selection of the most meritorious projects to implement biomedical research programs of the highest quality. Although a number of scientists from commercial organizations now serve on these advisory bodies, NIH has a special interest in adding greater representation from the small business scientific sector than now exists.

All nominations will be carefully considered; NIH reserves the right to make final selections.

Responsibilities

Each review group is composed of primarily non-Federal scientists selected for their competence in the particular scientific area for which that group has review responsibilities. Such responsibilities generally involve several days of intensive review of research proposals prior to a meeting of the review group. Specific applications are assigned in advance of the meeting to each member who prepares written detailed critiques prior to the meeting and leads discussion at the meeting.

Criteria for Membership

The primary requirement for serving on a scientific review group is demonstrated competence as an independent investigator in a research and development specialty in a laboratory or clinical setting. Assessment of such competence is based on the quality of research accomplished, proven ability to develop a product or process with commercial applications, and/or other significant scientific activities, accomplishments, and honors. Usually a doctoral degree or its equivalent is required. Service also requires mature judgment, balanced perspective, objectivity, ability to work effectively in a group context, commitment to complete work assignments, and assurance that the confidentiality of applications will be protected.

How to Respond to Request

Any person may nominate one or more highly qualified candidates for consideration. Self-nominations are acceptable. Nominations should be made promptly for immediate consideration, and at any time thereafter for future attention. Each nomination should be clearly identified as representing the small business sector.

For each nomination:

1. Provide full name of nominee, title, complete mailing address (including organizational affiliation), and telephone number.

2. In not more than two or three lines, provide in key words information concerning the nominee's scientific areas of experience, interest, and expertise.

3. Name, address, telephone number, and signature of nominator.

4. An updated and comprehensive curriculum vitae of the nominee.

The nominator may be contacted for more detailed information. Nominees should be informed prior to being nominated. They will be sent a packet requesting relevant information upon receipt of nomination.

Send information to:

NIH Consultant File Project
Suite 212
6400 Goldsboro Road
Bethesda, Maryland 20817

NOTICE

LETTERS OF INTENT

The use of letters of intent for certain types of applications for grants or cooperative agreements can be beneficial to both the awarding component and the applicant investigator/institution. Early interaction between prospective applicants and program staff can be very helpful in preparing complex or highly targeted applications and can often prevent delays resulting from the need to revise unresponsive or otherwise unsatisfactory applications. The letters also provide NIH with an indication of the number and types of applications to be submitted and the institutions that may be involved, facilitating planning for the review process. In general, letters of intent are most appropriately used for resource, center, and program project applications, and for single RFA solicitations. Applicants are urged to read the appropriate announcements carefully and follow suggestions concerning consultation with NIH staff.

Prospective applicants are reminded that letters of intent are not binding, nor can they ensure favorable review and funding decisions. Letters of intent cannot be used as a preliminary application nor required as a pre-condition for applying for any NIH award. As a general rule, the suggested content of the letter of intent will be limited to a brief description of the thrust of the envisioned research activity and the identity and basic qualifications of the key investigators. If specific eligibility requirements are spelled out in the announcement, prospective applicants may be asked to address these points in a letter of intent.

NOTICE

CANCER CONTROL SCIENCE PROGRAM

NATIONAL CANCER INSTITUTE

The National Cancer Institute announces that until new guidelines for the "Cancer Control Science Program" are written and approved, no new or revised applications will be accepted. The "Cancer Control Science Program" was announced in the March 26, 1982 edition of the NIH Guide for Grants and Contracts, Vol. 11, No. 4, pages 28-34. When the new guidelines are available, they will be published, together with information on the receipt dates.

NOTICE

NEW WORLD PRIMATE AVAILABILITY

As part of a major project in primate conservation and breeding, the Pan American Health Organization is providing services to South American countries in planning and operating wild primate management and primate breeding programs. These services are in part supported by the National Institutes of Health (NIH), in recognition of the need for international cooperation in conserving primates in their natural habitats as well as in research utilization. The Government of Peru has established a program at Iquitos to breed monkeys and from which primate surveys and population monitoring are conducted. As a consequence of these efforts, several species of primates are available to NIH grantees and contractors from Peru. These include:

Saimiri sciureus	(gothic and roman arch squirrel monkeys) - colony produced and wild caught
Cebuella pygmaea	(pygmy marmoset) - colony produced and wild caught
Aotus trivirgatus	(owl monkeys, Karyotype I) - colony produced and wild caught
Saguinus fuscicollis	(saddle-back tamarin) - wild caught
Saguinus mystax	(moustached tamarin) - currently wild caught; colony produced animals will become available

Services can also be made available to scientists for conducting field studies relating to nonhuman primates with the assistance of program staff at Iquitos. Access to the colonies maintained in Iquitos and to the laboratories maintained there can be provided as well as technical support for certain types of investigative work.

In order to assist Peruvian authorities in developing programs appropriate to meet future needs, users of New World primates are requested to inform the Interagency Primate Steering Committee (IPSC) of their projected requirements. Requests for animals and information concerning costs, and services that are available should be directed to:

Dr. Thomas L. Wolfle
Executive Director, IPSC
National Institutes of Health
Building 12A - Room 4003
Bethesda, Maryland 20205

Telephone: (301) 496-5424

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NIADDK-DEMD-83D-1

IMMUNOPATHOGENETIC MECHANISMS INVOLVED IN THE DEVELOPMENT OF INSULIN-DEPENDENT DIABETES MELLITUS (IDDM).

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES AND DIGESTIVE AND KIDNEY DISEASES

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: July 15, 1983

I. PURPOSE

The National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDK), the National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute of Child Health and Human Development (NICHD), invite investigator-initiated research grant applications to define the immunopathogenetic mechanisms associated with the etiology and pathogenesis of Insulin Dependent Diabetes Mellitus (IDDM).

II. DISCIPLINES AND EXPERTISE

The interdisciplinary nature of this study will require some combination of expertise in the areas of the immunology, genetics, etiology, pathophysiology and epidemiology of diabetes mellitus and its complications.

III. BACKGROUND

Diabetes mellitus and its complications are major public health problems in the United States today. The NIH sponsors broad based programs of basic and clinical research into the cause, cure and prevention of diabetes and its complications. In this regard, recent evidence for an altered immune response in the development of IDDM has prompted this solicitation in an effort to stimulate additional research in this area. Recent advances in immunology including identification of the various types of lymphocytes involved in the immune response, identification of the genetic basis for generation of unlimited numbers of antibodies, better understanding of the

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This program is described in the Catalog of Federal Domestic Assistance No. 13.847, Diabetes, Endocrinology, and Metabolism. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

complement system and the mechanisms of effective function of immunoglobulins, and new techniques and tools including the development of specialized radioimmunoassays, monoclonal antibodies, identification of HLA and tumor antigens associated with various diseases, etc., have contributed substantially to new concepts of the etiology and pathogenesis of IDDM. The exact role of the alteration in the immune response associated with the development of IDDM is not known but evidence such as lymphocyte infiltration in the pancreas, the presence of islet-cell-directed autoantibodies, association of specific histocompatibility markers with the disease, and the presence of certain viral infections around the time of onset of the disease continues to implicate an association between the immune response and the development of IDDM. These and related observations suggest that some environmental insult may trigger onset of the disease in individuals with a vulnerable immune system.

The NIADDK, NIAID, and NIDR sponsored a workshop in November 1980 which reviewed existing data and made recommendations for future initiatives which have been incorporated in the proposed scope of this solicitation.

IV. OBJECTIVES

This solicitation is prompted by a perceived need for additional new research to elucidate the immunopathogenetic mechanisms important in the development of IDDM and new basic information from population studies which relate these various factors to the incidence and prevalence of the disease and the development of its complications.

V. SCOPE

The primary objective of this solicitation is to encourage basic and clinical research on the involvement of the immune response in the etiology and pathogenesis of IDDM and its complications. However, the objective is not to encourage submission of applications proposing clinical trials to evaluate the potential therapeutic applicability of immunosuppressive agents in the prevention/treatment of IDDM.

Some examples of research topics which would be considered responsive to this solicitation include the following:

A. Etiology and Pathogenesis

1. Studies of the susceptibility gene(s), gene products, and their relationship to the immune system;
2. Studies of the role of viruses in the etiology and pathogenesis of diabetes including prospective collaborative viral studies of apparently unaffected siblings of subjects with IDDM and prevention of viral effects with a vaccine;
3. Studies of the role of autoimmune factors in the development of chronic complications (e.g., in the eye, kidney, heart, etc.);
4. Studies of the sub-sets of lymphocytes and their relationship to the development of IDDM.

B. Epidemiology

1. The acquisition of more standardized data on IDDM, including information on incidence, familial occurrences, pedigree studies, prevalence, and complications;

2. Studies of HLA genotypes and their association with diabetes;

3. Studies of the epidemiology of infectious diseases in diabetics to ascertain to what extent diabetics are more prone than non-diabetics to viral, bacterial, and mycotic infections, and what immune deficits or other factors are responsible for the predisposition of IDDM patients to these disorders;

4. Prospective collaborative studies of unaffected siblings of subjects with IDDM to ascertain their relative risk according to: HLA type; presence or absence of circulating autoantibodies; and titers of anti-viral antibodies.

C. Diagnostic Approaches

1. Study of anti-viral antibodies as a measure or predictor of diabetes;

2. Development of microcytotoxicity assays or other immunoassays to detect immune activity directed against the beta cell;

3. Standardization of testing for islet cell antibodies (ICA), and their subgroups such as islet cell surface antibodies (ICSA), and assessment of their pathogenesis.

D. Other

1. Development of animal models for use in studies of pathogenic factors in spontaneous, chemical or surgically induced diabetes;

2. Research in animal models on pancreatic tissue/beta cell transplantation and prevention of immune rejection.

These areas of interest are not listed in any order or priority. They are only examples of areas of research; other areas may occur to an applicant which are related to the scope described above.

VI. MECHANISM OF SUPPORT

The mechanism of support for this program will be the grant-in-aid. The regulations (Code of Federal Regulations, Title 42, Part 52 and as applicable to the state and local governments, Title 45, Part 74) and policies which govern the research grant programs of the National Institutes of Health (NIH) will prevail. Although this solicitation is included in the sponsoring Institute's funding plans for Fiscal Year 1984, support is contingent upon receipt of appropriated funds for this purpose. The sponsoring Institutes plan to designate a total of $1,000,000 for the support of applications submitted in response to this solicitation; however, the specific amount to be funded will depend upon the overall merit and scope of the applications received. It is anticipated that approximately eight to twelve grants will be awarded under this solication. Since a variety of approaches would represent valid responses to this solicitation, it is anticipated that there will be a range of costs among individual grants awarded. With respect to post-award administration, the current policies and requirements that govern the regular research grant programs of the NIH will prevail.

VII. REVIEW PROCEDURES AND CRITERIA

A. Assignment of Applications

Upon receipt, applications will be reviewed by staff for their responsiveness to the objectives of this RFA. If an application is considered unresponsive, the applicant will be contacted and given an opportunity to withdraw the application or to have it considered for the regular grant program of the NIH. If an application submitted in response to this RFA is identical to a research grant application already submitted to the NIH for review, the applicant will be asked to withdraw the pending application before the new one is accepted. Simultaneous submission of identical applications will not be allowed.

Applications will be received by the NIH, Division of Research Grants (DRG), referred to an appropriate Initial Review Group (IRG) for scientific merit review, and assigned to individual Institutes (see list above) for possible funding. Referral decisions will be governed by normal programmatic considerations as specified in the Referral Guidelines of the NIH, DRG.

B. Review Procedures

Applications in response to this solicitation will be reviewed on a nationwide basis, and in accord with the usual NIH peer review procedures. Applications will first be reviewed for scientific and technical merit by an IRG composed primarily of non-federal scientific consultants, and then by the National Advisory Council of the appropriate Institute(s). The review criteria customarily employed by the NIH for regular research grant applications will prevail.

C. Review Criteria

The factors to be considered in the evaluation of scientific merit of each application will be similar to those used in the review of traditional research project grant applications, including the novelty, originality, and feasibility of the approach; the training, experience, and research competence of the investigator(s); the adequacy of the experimental design; the suitability of the facilities; and the appropriateness of the requested budget to the work proposed.

VIII. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are encouraged to submit a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institutions. Such letters are requested for the purpose of obtaining an indication of the number and scope of applications to be received. A letter of intent is not binding, and it will not enter into the review of any application subsequently submitted. This letter should be received no later than June 15, 1983, and sent to:

Valerie P. Setlow, Ph.D.
Assistant Diabetes Research Program Director
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
Westwood Building - Room 605
5333 Westbard Avenue
Bethesda, Maryland 20205

B. Format for Applications

Applications should be submitted on form PHS 398, which is available from an applicant institution's Office of Sponsored Research or from the NIH, DRG. Use the conventional format for research project grant applications and ensure that the points identified in this RFA in the section on "Review Procedures and Criteria" are fulfilled. To identify the application as a response to this RFA, check "yes" on item two of page one of the application and enter the title "Immunopathogenetic Mechanisms Involved in the Development of IDDM" and the RFA number NIH-NIADDK-DEMD-83D-1.

As in the case with regular research project grant applications, applicants are requested to furnish their own estimates of the time required to achieve the objectives of the proposed research project. However, except under very unusual circumstances, applications submitted in response to this solicitation should not request support for more than a three year period. At the end of the initial award period, renewal applications may be submitted for further competitive review through the regular research grant program of the NIH.

C. Application Procedure

The original and six copies of the application should be sent or delivered to:

Application Receipt
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

D. Timetable

A letter of intent should be submitted no later than June 15, 1983.

Applications must be received by July 15, 1983. Any applications not received by this date will be considered ineligible for this special solicatation.

APPLICATION RECEIPT	INITIAL REVIEW	COUNCIL REVIEW	EARLIEST START DATE
July 15, 1983	Oct./Nov.	Jan./Feb.	April 1

E. Inquiries

For further information, investigators are encouraged to contact one or more of the following individuals:

Valerie P. Setlow, Ph.D.
Assistant Diabetes Research Program Director
National Institutes of Arthritis, Diabetes
and Digestive and Kidney Diseases
Westwood Building - Room 605
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7888

Robert A. Goldstein, M.D., Ph.D.
Chief, Allergy and Clinical Immunology Branch
National Institute of Allergy and
Infectious Diseases
Westwood Building - Room 755
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7104

Richard E. Horton, M.D.
Medical Officer, Clinical and Epidemiology
Studies Branch
Microbiology and Infectious Diseases Program
National Institute of Allergy and
Infectious Diseases
Building 31 - Room 7A49
Bethesda, Maryland 20205

Telephone: (301) 496-5893

Gilman Grave, M.D.
Chief, Nutrition and Endocrinology Section
Clinical Nutrition and Early Development Branch
National Institute of Child Health and
Human Development
Landow Building - Room C709
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-5575

CLINICAL INVESTIGATOR AWARD

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: September 15, 1983

I. PURPOSE

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of Clinical Investigator Awards. The clinical investigator award program is intended to:

- encourage newly trained clinicians to develop clinical and basic research interests and skills in the areas of cardiovascular, pulmonary, or blood diseases and the blood banking sciences;
- increase the pool of physician investigators in the areas of cardiovascular, pulmonary, or blood diseases and the blood banking sciences.

These awards provide the opportunity for clinically trained physicians with a commitment to research to develop into independent biomedical research investigators.

The award will enable candidates to undertake up to five years of special study and supervised experience tailored to individual needs with a sponsor (or sponsors) competent to provide research guidance. This award is intended to cover the transition between postdoctoral experience and a career in independent investigation. The clinical investigator award differs from the National Institute of Health (NIH) Research Career Development Award (RCDA) in that it seeks to develop research ability in individuals with a clinical background early in the candidate's career rather than to promote the further development of research skills of individuals already demonstrating significant research achievement.

II. BACKGROUND

Despite a recent decline in the death rate from coronary heart disease, cardiovascular disease continues to be the number one cause of death in the United States. Arteriosclerosis and hypertension account for almost one million deaths annually. An estimated 40 million Americans have diseases of the heart and blood vessels, resulting in a large burden of acute and chronic illness and disability. Heart and blood vessel diseases cost the economy more than $50 billion per year in

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This program is described in the Catalog of Federal Domestic Assistance Nos. 13.837, 13.838, and 13.839. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

vessels, resulting in a large burden of acute and chronic illness and disability. Heart and blood vessel diseases cost the economy more than $50 billion per year in wages, lost productivity, and expenses for medical care.

Diseases of the lung constitute a major national health problem. An estimated 10 million Americans, both young and old, are currently affected by these diseases with an annual estimated cost to the nation of over $29 billion. About one in every five persons has some chronic respiratory problem. In the newborn, the most common cause of death is neonatal respiratory distress syndrome. Neonatal RDS is implicated in the development of adult respiratory diseases as well. Fibrotic and immunologic lung diseases are major causes of lung problems in the young adult and may cause chronic obstructive pulmonary diseases. Of the adult respiratory diseases, emphysema and chronic bronchitis are the major causes of death.

Asthma, emphysema and chronic bronchitis represent particularly pressing health problems, since the death rate and prevalence of these conditions have increased at an alarming rate over the past 15 years. As a disabling disease, emphysema is a leading cause of worker retirement on Social Security disability payments.

Diseases of the blood underlie, or are critical contributors to, many disorders that affect mankind. As a consequence, they are major causes of death and disability in the United States. Until recently, no valid estimate of their adverse economic impact could be realistically made because disorders of the blood affect not only the blood itself but also the organs and tissues through which it flows. Recent research findings have revealed the widespread involvement of thrombosis in the pathology of numerous disorders; more aggressive therapy for cancer has resulted in increased susceptibility of patients to bleeding disorders; and many blood disorders either cause or accompany various types of diseases and injuries or result from them. A significant segment of the population has hemolytic disorders and anemias.

Recent studies have also provided data with which reliable estimates can be made about the quantities of blood collected, processed, and transfused and about the numbers and types of patients who receive transfusions. Discoveries of the biological properties of blood constituents during the past decade have greatly expanded the scope of health benefits derived from human blood donations through the use of components in increasingly specialized and effective therapy.

The clinical investigator award program is designed to encourage recently trained physicians to develop their clinical and basic research interests and research capabilities in heart, lung, or blood disease* areas. To help support the transition from clinical training status to that of a productive research investigator, the clinical investigator award will provide early support for clinicians with potential for developing into independent researchers.

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* The term "blood diseases" covers research into many aspects of bone marrow function and disorders of the red cell, megakaryocyte, platelet, and coagulation systems. Research on disorders of white cells, including the leukemias and other blood malignancies, and basic immunology related to the lymphoid system are the responsibility of other Institutes of the NIH and therefore cannot be supported through this mechanism.

III. IMPLEMENTATION

Beginning in Fiscal 1980, under the authorizations in the Public Health Service Act, Section 301(c) and Section 413(a), the NHLBI has funded clinical investigator awards. Each grant has a duration of five years and is non-renewable. Funding beyond the first year of the grant is contingent on satisfactory progress during the preceding year.

The status of the clinical investigator award program will be reviewed four years from the date of the first awards to determine whether the program should be continued. In addition, to assess the effectiveness of the program in fulfilling its objectives, the Institute intends, after completion of each grant, to follow the progress of the recipient for a period of five years to determine: (1) the investigator's professional affiliation(s), (2) his/her record of subsequent grant or contract support, and (3) his/her record of scientific publications. It is anticipated that the experience and results achieved by the awardee from this special grant program, in the majority of cases, will provide the basis for successful competition in the regular research support programs of the Institute.

The receipt date for applications will be September 15, 1983. The applications will be evaluated by an initial review group and by the National Heart, Lung, and Blood Advisory Council. The earliest start date for successful applicants will be July 1, 1984.

IV. PROVISIONS OF THE AWARD

The clinical investigator awardee will be supported for a period of five years. All funds must be used to support the original awardee. Support is based on a full-time, twelve-month appointment. The awardee will be provided salary support of up to $30,000, plus fringe benefits. The actual salary must be consistent with the established salary structure of the institution for persons of equivalent qualifications, experience, and rank.

Up to a total of $10,000 annually may be provided for supplies, equipment, travel, etc., which are necessary for pursuit of the awardee's research program. An appropriate sponsor must assume responsibility and provide guidance for the development of the candidate's research program.

Institutions may apply for awards on behalf of named individuals meeting the criteria for this award. Evidence of the commitment of the institution and sponsors to the candidate's research and career development is to be included in the application.

The grant will be made annually to the awardee's parent institution for each of the five annual budget periods. Costs allowed may include:

1. Awardee's Salary

   Up to a maximum of $30,000 for full-time support; in addition, fringe benefits will be provided. Institutional supplementation is permitted.

2. Research Support

Up to a maximum of $10,000 per year.

a. Equipment: specialized research equipment essential to the proposed program. The available facilities should include most of the necessary equipment;

b. Supplies: consumable supplies essential to the proposed program;

c. Travel: domestic travel essential to the proposed program;

d. Tuition for training courses: if essential to the awardee's individual research development program; and

e. Other: publication costs, patient costs, technical help, etc., necessary for the research program.

3. Indirect Costs

Funds will be provided for the reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees, and expenditures for equipment.

V. ELIGIBILITY

A. The award is designed to provide intensive, supervised research experience for clinicians. Thus, candidates are restricted to those holding health-professional degrees in the clinical sciences (M.D., D.O., or equivalent). Candidates ordinarily will have completed their clinical experience by the time the award can be made. Ordinarily a candidate in the following categories will not qualify:

1. with more than six years of postdoctoral experience at the time of award;

2. with previous independent NIH research support or its equivalent;

3. with less than three years total postdoctoral clinical experience at the time of the award.

In exceptional circumstances, individuals in one or more of the above categories may qualify for the award. However, the applicant must provide sufficient justification for such an exception.

Candidates should have broad clinical training, should demonstrate individual competence in clinical activities, and should show research potential in the chosen area of interest. Candidates must provide evidence of a serious intent for research and academic careers.

B. Applicants for a Clinical Investigator Award may not submit a concurrent application for an NIH Research Career Development Award, Academic Award, or for a New Investigator Research Award. A Clinical Investigator Awardee may subsequently apply for a research project grant.

C. The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established research and training programs, adequate numbers of highly trained faculty in clinical and basic science departments, and commitment and capability to provide guidance to clinically oriented individuals in the development of independent research careers.

Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation, and potential for a research career. Evidence of the commitment of the institution to the candidate's research and development must be provided.

D. Candidates must have one or more sponsors or advisors who are recognized as accomplished investigators in the research proposed at the applicant's institution. The sponsor must provide: 1) his/her concept of a development and research plan for the awardee; 2) his/her curriculum vitae (updated) with complete bibliography and research support; and 3) a letter indicating his/her evaluation of the proposed awardee and his/her willingness to provide guidance and support.

E. Candidates must provide a description of the proposed research and career development plan for the five-year period of the award. The candidate must be prepared to commit full-time effort to the objectives of this award. It is required that a minimum of 75 percent effort be devoted to the research program. The balance of effort can be devoted to other clinical and teaching pursuits only if they are consonant with the program goals, i.e., the awardee's development into an independent biomedical research investigator.

F. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of the third year of support. This report is to contain specific information concerning progress and accomplishments and, in particular, an appropriately detailed research plan and protocol.

G. Candidate must agree to inform the NHLBI annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

H. Candidates for an award must be citizens or non-citizen nationals of the United States or its possessions and territories or must have been lawfully admitted to the United States for permanent residence at the time of application.

VI. APPLICATION

Applications must be submitted on form PHS 398 which is available at the grantee institution. The original and 21 copies of the application should be clearly labeled "NHLBI CLINICAL INVESTIGATOR AWARD PROGRAM."

The chairperson of the department sponsoring the candidate should submit, a signed statement, as part of the application, detailing the department's commitment to the candidate during the term of the award.

The original and six complete copies of grant applications should be mailed to the following:

Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

Fifteen additional copies should be mailed at the same time to the Executive Secretary, Research Manpower Review Committee. Upon receipt of each application at NIH, a postal card acknowledging receipt will be mailed to the applicant.

The applicant should ask three present or former supervisors or preceptors to send a letter to:

Executive Secretary
Research Manpower Review Committee
Review Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building - Room 550
5333 Westbard Avenue
Bethesda, Maryland 20205

The applicant should attest to his/her potential for conducting independent research. The applicant is responsible for making necessary arrangements to ensure that the reference letters are mailed by the supervisors/preceptors directly to the Review Branch for receipt by September 15, 1983.

Applications for this award are due September 15, 1983. The earliest start date for awards is July 1, 1984.

VII. REVIEW CRITERIA

Applications for clinical investigator awards will undergo initial merit review in the Review Branch, Division of Extramural Affairs, NHLBI. Secondary review will be by the National Heart, Lung, and Blood Advisory Council. Criteria for review include:

1. The candidate's potential for a career in independent research;
2. The candidate's commitment to a research career;
3. The eligibility of the candidate as defined in the program announcement;
4. The overall merit of the candidate's five-year plan for research and the development of research skills;
5. The quality of the candidate's clinical training and experience;
6. The institution's ability to provide quality facilities, resources, and opportunities necessary to the candidate's research development;

7. Presence of highly trained faculty in clinical and basic science departments relative to the area of study; and

8. The ability and plans of the sponsor (or sponsors) who will provide the candidate with the guidance necessary for career development in research.

VIII. NHLBI STAFF CONTACTS

Inquiries about the program should be directed to:

Research Training and Development Officer
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 514A
Bethesda, Maryland 20205

Telephone: (301) 496-1817

Research Training and Development Officer
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A-08
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Research Training and Development Officer
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 6A-05
Bethesda, Maryland 20205

Telephone: (301) 496-7668

Letters of reference, inquiries regarding review procedures, and 15 copies of the application should be directed to:

Dr. Carol Lentendre, Executive Secretary
Research Manpower Review Committee
National Heart, Lung, and Blood Institute
Westwood Building - Room 550
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7361

ANNOUNCEMENT

RESEARCH ON BENIGN PROSTATIC HYPERPLASIA

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) announces a continuing interest in basic and clinical research on Benign Prostatic Hyperplasia (BPH).

I. BACKGROUND

BPH is a condition characterized by excessive growth at the center of the prostate gland which reduces urine flow by direct obstruction and by altering the function of the outlet mechanism. Microscopic evidence of BPH has been seen as early as age 20, and may become symptomatic in about 45% of men by the age of 45. Estimates of the incidence of BPH vary between 80-100% in men over the age of 65. Morbidity and interference with daily functioning is appreciable. The disorder has been reported to occur more frequently, and about 10 years earlier in the black male. BPH may or may not be progressive, but has been noted to reoccur in 3-10 years following surgery in some patients. It is estimated that there is a 10% probability that a man of 40 will require prostatic surgery for BPH if he lives to be 80 years of age. The medical costs of BPH have been estimated to exceed one billion dollars per year.

II. OBJECTIVES AND SCOPE OF RESEARCH

The goals of research on BPH are to increase knowledge about the etiology of the stromal and epithelial proliferation, underlying mechanisms governing the distribution of the enlargement and the progression of the disease to determine if preventive measures and/or adequate medical alternatives to surgical treatment may be developed.

The research topics noted below are only examples and should not be construed as limiting scientific proposals to those areas of research. Some of the areas for continuing and for new research are listed below. Innovative research is needed and the list is by no means all-inclusive. Specific hormonal and biochemical events have been associated with abnormal growth of prostatic tissue both in the canine model of BPH and in man, and such studies are of continuing interest. Less well

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This program is described in the Catalog of Federal Domestic Assistance No. 13.849, Kidney Disease, Urology, and Hematology Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

explored has been the area of possible prostatic-growth factors in normal and/or abnormal prostate tissues, and how such factors might relate to the known hormonal-biochemical environment in BPH. Studies concerning agonists and antagonists to prostatic growth, pituitary contributions to prostatic growth or epithelial-stromal cell interactions are of importance. Studies of the physical factors influencing the position and distribution of the growing masses, especially in relation to the vesical neck mechanism are relevant, as are those concerning neuromuscular responses. In addition, basic controlled studies are needed on urodynamic parameters to detect early obstruction and monitor response to therapy. The NIADDK is interested in all innovative research concerning the onset, progression and treatment of BPH.

III. MECHANISMS OF SUPPORT

Applications may be submitted for any of the conventional National Institutes of Health (NIH) grant support mechanisms. Appropriate application kits and information on applying for a research grant may be obtained from the institution's grant office, or by writing or calling:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7441

When applying to the Division of Research Grants (DRG) the applicant should make specific note in item 2, Part 1 of the application, "Prepared in Response to the NIADDK Program Announcement: Research on Benign Prostatic Hyperplasia." A covering letter stating that the application is in response to this announcement also should be enclosed with the application. The original application and six copies should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

A copy of the application with covering letter should be mailed to the NIADDK at the same time the proposal is submitted to the DRG. Applications will be reviewed for scientific merit by an appropriate initial review group in the DRG, NIADDK, depending on the support mechanism being sought. Review will be conducted in compliance with NIH policy and procedures involving peer review. Awards will be made on a competitive basis.

IV. INQUIRIES AND CORRESPONDENCE

Requests for information, letters of intent and copies of applications should be directed to:

Charles H. Rodgers, Ph.D.
Urology Program Director
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
Westwood Building - Room 621
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7574

ANNOUNCEMENT

NOTICE OF AVAILABILITY OF REQUEST FOR TRAINING GRANT APPLICATIONS: RFA

RFA-NIH-NLM-EP-83-1

HEALTH COMPUTER SCIENCES RESEARCH TRAINING

NATIONAL LIBRARY OF MEDICINE

Application Receipt Date: August 1, 1983

PURPOSE AND OBJECTIVES

The National Library of Medicine (NLM) has prepared a Request for Application (RFA) for training grant proposals in a single competition for postdoctoral research training in the health computer and information sciences. Such training will help meet a growing need for qualified talented investigators, well equipped to address fundamental issues in the management of health knowledge. These investigators will contribute to the growth of science by their studies of the role of knowledge in professional life, by analyses of social structures for managing this knowledge, and by advancing the frontiers of the computer sciences for organizing, retrieving, and utilizing health knowledge. It is also intended to foster the health computer sciences and health information sciences as a growing discipline with an appropriate place in academic medicine. It is expected that trainees will become able cross-disciplinary translators, taking the computer sciences to all of medicine.

It is expected that the core of training will emphasize the synthesis, organization, and effective utilization of knowledge. The curricula should be multidisciplinary--involving medicine, the cognitive sciences, information science, and computer science. It is intended to support programs at training sites which offer an excellent setting for didactic instruction, involvement in major, on-going health computer science studies, and opportunities for work in advanced information science research. It is expected that the training programs will therefore demonstrate an ability to recruit persons with high potential for academic research careers. The trainees should be recognized as potential scientific leaders, able to build new departments and strengthen existing ones. Trainees should leave the programs well versed in advanced mathematics, biostatistics, and methods of computational inference. Although candidates for training should be clearly destined for health research careers in this field, their doctorates may have been earned in any appropriate field of endeavor, such as medicine, dentistry, nursing,

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This program is described in the Catalog of Federal Domestic Assistance, Medical Library Assistance No. 13.879. Grants will be awarded under the authority of the Public Helth Sevice Act, Section 393 (42 USC 280b-4) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

computer science, or any of the biological sciences. The objective is to sponsor the kind of training that can attract highly talented candidates from the most eminent universities and professional schools. Training sites should be academic medical centers, although consortium training arrangements with other graduate schools and institutions are encouraged. These grants will enable established investigators of national stature to attract the most promising junior scientists and future collaborators.

MECHANISM OF SUPPORT

Depending on the obligations required for the termination of currently active training programs, NLM plans to make available up to $600,000 for new grants in this program in FY 1984. In addition, actual award of grants pursuant to this RFA is necessarily contingent upon receipt of appropriated funds for this purpose. However, it is expected that four to six training grants will be awarded in FY 1984 or possibly in early FY 1985. The specific number will also depend on the merit and scope of applications received, as well as the availability of funds.

These awards are authorized by the Medical Library Assistance Act and are not part of the National Research Service Awards Program of the PHS. However, the policies and requirements of the NLM program are similar to PHS NRSAs. Annual stipend levels for trainees are determined by the number of years of relevant postdoctoral experience at the time of appointment. Research experience, including industrial, teaching, internship, residency, etc., may be considered relevant experience. Interested applicants may refer to NRSA guidelines for allowable stipend levels, related trainee expenses, and institutional support costs.

STAFF CONTACT

Inquiries about the program and requests for copies of the RFA may be directed to program officials at:

Biomedical Information Support Branch
Extramural Programs
National Library of Medicine
Bethesda, Maryland 20209

Telephone: 301 - 492-4221

NOTICE

PROGRAM PROJECT RESEARCH GRANT

APPLICATION (P01) SPECIAL DIRECTIVES

NATIONAL INSTITUTE ON AGING

The National Institute on Aging (NIA) announces special instructions for investigators submitting applications for Program Project Research Grants (P01s) which are likely to be assigned to NIA for support. These directives will apply to all new and competing program project applications submitted for the NIH-DRG application receipt date, June 1, 1983, and thereafter. This announcement supersedes the previous announcement issued in the NIH Guide for Grants and Contracts, Vol. 10, No. 11, October 9, 1981.

Program project grants are regarded by the National Institute on Aging (NIA) as a means for encouraging multidisciplinary or multifaceted approaches to the investigation of complex biomedical, behavioral and social problems of aging. A program project grant should be one in which such collaborative and cooperative research efforts accelerate the acquisition of knowledge more effectively than does a simple aggregate of research projects. There should be benefits in intellectual and scientific development, cost-effectiveness, and interdisciplinary innovation both to the investigators and to the NIA and which are not possible through other support mechanisms.

I. DEFINITION

A program project grant is a mechanism for the support of a broadly based research effort that has a well-defined, central research objective. The hallmark of a successful program project is an integrated research program where the interrelationship of individual scientifically meritorious projects will result in a greater contribution to the goals of the overall program than if each project were pursued individually. Responsibility for the goals, organization, administration and conduct of a program project lies with a principal investigator, who is usually an established investigator in the field. Each individual research component within the program project is under the leadership of a researcher with independent standing. Often, a program project will also include provisions for facilities such as administrative, clinical, laboratory, equipment, and/or animal cores, which are shared by more than one project within the program project as a whole.

II. DISTINGUISHING FEATURES OF A PROGRAM PROJECT

A. It is expected that a substantial commitment of time and of institutional resources will be made by the applicants.

B. The principal investigator must possess recognized scientific and administrative competence, a commitment to aging research, and must be prepared to exercise leadership in the maintenance of the quality of all proposed research.

C. There must be a unified, well-defined goal or problem area of research to which each project relates and contributes, thereby producing a research environment that promotes interactions.

D. There should be a clear rationale for and advantage from any proposed "cores" with a clearly defined outline of their relationship to each project.

E. A mechanism for formalized interactions at regular intervals should be proposed, and provisions for collecting, pooling, analyzing and relating data from each project should be detailed.

F. Each individual research project must, as assessed by peer review, both stand on its own scientific merit and complement other projects wherever feasible. Thus, a project regarded as highly meritorious in isolation might be recommended for deletion from the program if it is seen as being totally independent from the program as a whole. Conversely, a project recommended for approval with a low degree of enthusiasm nevertheless may be retained if it provides a service or is otherwise important to the program as a whole.

G. The proposed research must meet a programmatic need in a priority area of interest. In keeping with the above, program projects ordinarily should be in the priority areas listed below, or as amended in future announcements. The Institute recognizes, however, that interdisciplinary research approaches relevant to the Institute's mission can and do arise outside areas defined by published announcements. In all cases the first action on the part of an investigator should be to communicate with an appropriate program official. Consultation in the development of a program project application is available from the following offices, depending on the subject matter of the proposed research:

Associate Director for Biomedical Research
and Clinical Medicine
National Institute on Aging
Building 31 - Room 5C-11
Bethesda, Maryland 20205

Telephone: (301) 496-4996

Associate Director for Behavioral Sciences
Research
National Institute on Aging
Building 31 - Room 5C-05
Bethesda, Maryland 20205

Telephone: (301) 496-3136

III. PRIORITY AREAS IN BIOMEDICAL RESEARCH AND CLINICAL MEDICINE

A. General Programmatic Areas

1. Nutrition in relation to health of the aged and aging processes
2. Pharmacology
3. Gerontological and geriatric dermatology
4. Differentiated cells in culture for the study of age-related functional alterations
5. Senile dementia of the Alzheimer's type

6. Geriatric research, e.g., urinary incontinence, infectious diseases, epidemiological studies
7. Animal models of aging
8. Immunology
9. Exercise physiology as it affects age-related adaptation

B. Teaching Nursing Home (TNH). See Program Announcement in NIH Guide to Grants and Contracts, Vol. 10, No. 12, November 6, 1981, for a descriptive overview of the research scope and content of TNH applications.

IV. PRIORITY AREAS IN BEHAVIORAL SCIENCES RESEARCH

A. Studies in the maintenance and promotion of health and effective functioning in the middle and later years (e.g., specification of the psychosocial processes, interacting with biomedical processes, that can extend the productive middle years of life by preventing, postponing, or reversing current disabilities of old age. This includes such topics as work and retirement, health institutions, coping and social support, health behaviors and attitudes, family and household). See NIH Guide for Grants and Contracts, Vol. 10, No. 10, September 4, 1981.

B. Cohort-longitudinal studies which serve as the data base for interdisciplinary research and potentially for secondary data analyses.

V. POLICY STATEMENT

The following policies shall apply to program project applications:

o The resolution of issues regarding compliance with overall policy and procedures for program projects will be the responsibility of the NIA Associate Director for Planning and Extramural Affairs.

o The total direct costs requested should not exceed $500,000 for the first year, and the total for a five-year period should not exceed $3,000,000. Budget increments for subsequent years may include some necessary cost-of-living increases.

o The principal investigator must be in charge of at least one individual component research project or core other than the administrative core.

o To be eligible for award as a program project, an approved application must contain a minimum of three research subprojects, including that of the principal investigator, in addition to any core projects.

o Program projects submitted as proposals for TNH have additional requirements for interinstitutional collaborations and a limit of core expenses to $125,000 per year. Prospective applicants for this award should consult the NIA TNH Announcement in the NIH Guide for Grants and Contracts, Vol. 10, No. 12, November 6, 1981. Copies may be obtained from the Associate Director for Biomedical Research and Clinical Medicine at the address above.

- Initial applications may be submitted for up to a five-year period and can be renewed for a subsequent five-year period. The maximum total project period award is ten years. This limit shall be effective starting with the June 1, 1983, deadline.

VI. APPLICATION PROCEDURES

All applicants are encouraged to communicate with NIA at least two months prior to preparation of a formal application through a "letter of intent" submitted by the prospective principal investigator. This letter of intent will assist NIA staff to determine whether the applications falls within the mission and research interests of the Institute and meets the criteria for a program project. It will also provide an opportunity for the applicant to consult with NIA staff.

The letter of intent should provide, in no more than three single-spaced, typewritten pages, the following information:

1. A statement highlighting the central theme and objectives of the proposed program project and discussing the rationale for use of the program project mechanism;
2. A brief description of each subproject including the name of the project director and a statement of how each specific subproject will contribute to the overall goal of the program project;
3. Brief biographical data for th principal investigator and key staff.

If the prospective applicant anticipates that the budget will exceed the cost limits cited above, this should be addressed in the letter of intent.

Letters of intent should be mailed to the Associate Director for Biomedical Research and Clinical Medicine Program or the Associate Director for Behavioral Sciences Research Program, NIA, depending on the primary emphasis of the proposed program project application.

At the same time, a copy of the letter of intent should be sent to the Scientific Review Office, Office of Planning and Extramural Affairs, NIA. (See next page for complete address.)

In response to the letter of intent, potential applicants will be contacted promptly by an Institute health scientist administrator who will be available for further consultation.

Applications should be prepared on form PHS 398 (Revised 5/82), which is available at most institutional business or research offices, or from the Division of Research Grants, NIH. On Page one, item two, type "PROGRAM PROJECT" on the application. "Teaching Nursing Home" should also be noted in this space, if appropriate. NIH-DRG receipt and review dates for a program project application are:

Application Receipt Dates	Initial Review	Council Review	Earliest Beginning Dates
February 1	June	September October	December 1
June 1	October November	January February	April 1
October 1	February March	May	July 1

The page limitations stated in PHS 398 kit instructions should be applied to the individual project descriptions, not to the entire program project application as a whole. Complete information, including budget, should be provided for each component project. In addition, overall program budgets (including core facilities where applicable) should be provided with the overview section of the proposal. The total program project application may not exceed 300 pages in length. Appendix materials should be kept to a minimum, and in no case should they exceed the length of the project that they support. Applications exceeding these limits may be returned to the applicant without review. NIA program staff should be consulted prior to submission if questions exist about the preparation of an application.

Several weeks prior to mailing, it is to the applicant's advantage to notify NIA program officials that a completed, formal application will be submitted.

Applications should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

At the time the formal application is mailed to DRG, the applicant also should inform the Chief, Scientific Review Office, NIA, in writing, that his/her program project application has been submitted to DRG. The address is:

Scientific Review Office
Office of Planning and Extramural Affairs
National Institute on Aging
Building 31 - Room 5C-06
Bethesda, Maryland 20205

It would be desirable to include two copies of the application itself with the letter of notification.

VII. REVIEW PROCEDURES AND CRITERIA

A. Introduction

A grant application assigned as a program project to the NIA will be reviewed by an NIA Initial Review Committee (IRC) managed by the Scientific Review

Office, Office of Planning and Extramural Affairs. In addition to providing scientific merit review, the Committee ensures that all NIA program projects are evaluated in a uniform, consistent fashion.

The steps in the review process *may* include a project site visit to evaluate the overall merit of the application. However, all applications should be complete in themselves and should be prepared as if a site visit were not to be made. If a site visit is conducted, the project site visit team generally includes regular members of the IRC as well as other *ad hoc* consultants who have expertise in each area of the proposed program. Except in circumstances when the site visit team is a Special Review Committee, the report of the team is brought before and acted upon by the IRC. The final recommendation for all program project applications assigned to NIA is made by the National Advisory Council on Aging.

B. Review Criteria

The program project grant application should include a justification for the appropriateness of that support mechanism. Review criteria include evaluation of the following, not necessarily in order of importance.

- The scientific merit of the program as a whole, as well as that of each individual project. Each project should be supportable on its own merit.
- The significance of the overall program goals and the development of a well-defined cental research focus of clear importance and relevance to the goals and mission of the NIA.
- The cohesiveness and multidisciplinary or multifacted scope of the program and the coordination and interrelationships among the individual projects and core(s). Also, the relationship of the core(s) to the central focus of the overall program.
- The justification for and usefulness of the core facilities to the various research projects. Each core unit must provide essential facilities or services for two or more approved individual projects.
- The leadership, scientific ability, and administrative competence of the principal investigator and his or her commitment and ability to devote substantial time and effort to the program.
- The qualifications, experience, and commitment of the investigators responsible for the individual research projects or core(s) and their contribution to the program, including their ability to devote adequate time and effort to the program.
- Accomplishments of the program to date (for renewal and supplemental grant applications).
- The academic and physical environment in which the research will be conducted, including the availability of space, equipment, research subjects, and the potential for interaction with active scientists from other departments and/or institutions.

- A sound administrative and organizational structure that facilitates attainment of the objective(s) of the program.

- Arrangements for internal quality control of ongoing research, allocation of funds, day-to-day management, internal communications and cooperation among the investigators involved in the program, contractual agreements, and replacement of the principal investigator, if required, on an interim or permanent basis.

- The institutional strength, stability, and commitment to research and to the program, including fiscal responsibility and management capability to assist the principal investigator and staff in following PHS plicy.

- The appropriateness of the period of support and budget requested in relation to the proposed program.

- The ethical and hazardous aspects of the projects.

C. Review Committee Recommendation

The IRC will consider all of the above factors, and will vote a priority score for projects and budgets recommended for approval. In this regard, it is important to note that the judgment of the principal investigator in including marginal projects in an application will be an important consideration in arriving at an overall recommendation. It is to the applicant's advantage, therefore, to limit submission of projects to only those with the highest individual as well as collective merit.

D. Review by Council

The last step in this process is a final review action by the National Advisory Counil on Aging. Factors considered in the review include:

- The results of the initial review for scientific and technical merit;

- The significance of the research program to the fields of gerontology and geriatrics;

- National needs and program balance;

- Policy and budgetary considerations; and

- Program relevance to the goals and mission of the Institute.

NOTICE

PUBLIC MEETING ON LABORATORY ANIMAL CARE AND USE

The National Research Council's Institute of Laboratory Animal Resources (ILAR) will hold an open meeting on May 17, 1983, beginning at 9:00 a.m., to receive statements from the public relevant to its preparation of a sixth edition of the Guide for the Care and Use of Laboratory Animals. The meeting will be held in the auditorium of the National Academy of Sciences, which is located in the 2100 block of "C" Street, N.W., Washington, D.C.

The revision of the "Guide" is being carried out under contract to the Academy from the National Institutes of Health by a 14-member Committee on Care and Use of Laboratory Animals, chaired by Dr. Steven P. Pakes of the University of Texas Health Sciences Center, Dallas, Texas.

Oral presentations must be scheduled by the ILAR office and will be limited to five minutes each in order to accommodate as many speakers as possible, while allowing the committee ample time for questions. Each oral presentation should be accompanied by a written statement, which may be of any length. Twenty (20) copies of the written statement should be provided to the Committee at the meeting. To request scheduling write to:

Dr. Earl W. Grogan
ILAR, National Research Council
2101 Constitution Avenue, N.W.
Washington, D.C. 20418

Requests must be received on or before April 29, 1983. Written statements from those who do not speak at or who do not attend the public meeting will be accepted any time at the above address. All statements will be made available to the Committee.

Two additional regional public meetings are planned, one in the mid-west, and one on the west coast. Public announcements will be made for these meetings when the locations and schedules are selected.

Parking for meeting participants is not available at the Academy building.

NIH Guide
for Grants and Contracts

Vol. 12, No . 5, May 20, 1983

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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National Institutes of Health

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

The 1983 edition of NIH Extramural Programs: Funding for Research and Research Training is now available. Limited distribution is being made to all institutions/organizations receiving National Institutes of Health (NIH) awards. Those individuals or institutions wishing to obtain one or more copies may purchase them for $5.50 each by writing to:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

Please specify GPO Stock No. 017-040-00487-7. Checks should be made payable to the Superintendent of Documents.

ERRATUM

An incorrect telephone number was listed in the following Announcement printed in the NIH Guide for Grants and Contracts, Vol. 12, No. 4, April 22, 1983:

Announcement - Notice of Availability of Request for Training Grant Applications: RFA - RFA-NIH-NLM-EP-83-1 Health Computer Sciences Research Training

National Library of Medicine

At the bottom of page 22 the correct telephone number should be:

(301) 496-4221

NOTICE

REMINDER TO RECIPIENT INSTITUTIONS

NATIONAL RESEARCH SERVICE INSTITUTIONAL TRAINING GRANTS

PHS policy requires that a Statement of Appointment (PHS Form 2271) be received by the NIH awarding unit before any stipend is paid to a trainee. The actual practice of the submission of these forms has become irregular. It is incumbent upon us all to keep the system accurate, especially in these stringent budgetary times when research training funds are in unusually short supply. Your attention is called to the fact that stipends paid from institutional research training grants prior to the submission of an appointment form may be disallowed.

We ask the assistance of Program Directors and Business officials in the prompt submission of these forms. For this purpose, we restate the policy in this matter as originally published in the NIH Guide for Grants and Contracts Special Edition, Vol. 11, No. 7, June 18, 1982, National Research Service Awards.

> "Statement of Appointment (Form PHS 2271)
> The Institution must submit this form to the awarding unit at the start of each trainee's appointment or reappointment. No stipend or other allowance may be paid until the appointment form has been submitted along with a signed Payback Agreement. It is important to note that the information on the Statement of Appointment and the Termination Notice is the basis for determination of the length or amount of an individual's payback requirement. The program director and the institutional financial officials should coordinate the information reported on the Statement of Appointment. It should be treated as a financial document for obligating costs (stipends) which later are reflected as part of the total costs in the Financial Status Report."

NOTICE

NOTICE OF POLICY CHANGE

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRTION

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

ALCOHOL RESEARCH CENTERS PROGRAM

February 1983

This notice describes a recent policy change regarding the level of support for National Alcohol Research Centers of the National Institute on Alcohol Abuse and Alcoholism. The changes are applicable to grant awards made under this program and became effective February 1, 1983. This program is authorized under Section 504 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act.

Change in Maximum Level of Support

The maximum annual grant award for the support of a new National Alcohol Research Center will be $1,000,000, which includes direct and indirect costs, for each year except the initial year. The first year of support will remain at a maximum of $500,000 including direct and indirect costs. For currently funded Centers, the maximum level of support will be effective after December 1, 1983.

REQUEST FOR COOPERATIVE AGREEMENTS APPLICATIONS: RFA

NIH-NCI-DCCP-BCB-83-3

INFECTIOUS ETIOLOGY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) AND KAPOSI'S SARCOMA

NATIONAL CANCER INSTITUTE

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: August 1, 1983

The National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID) invite applications for Cooperative Agreements from interested investigators for both basic and applied studies designed to determine the etiology of acquired immune deficiency syndrome (AIDS) and its associated aggressive generalized form of Kaposi's sarcoma. The determination of etiology may make possible the development of appropriate methods for eventual prevention and/or control of the disease.

Cooperative Agreements are awarded to both nonprofit and profit organizations and institutions. This type of solicitation is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the NIH and where substantial programmatic involvement by staff is anticipated. Applicants funded under the RFA are supported through cooperative agreements. The RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to the RFA will be reviewed by the same NIH Initial Review Group (IRG) and by the National Cancer Advisory Board and/or the National Advisory Allergy and Infectious Diseases Council. The specific deadline for the receipt of response to the RFA is August 1, 1983. Applications should be prepared and submitted in accordance with the aims and requirements of the following sections:

I. Background Information
II. Research Goals and Scope
III. Mechanism of Support
IV. Nature of Collaboration with NCI/NIAID Staff: Terms of Award
V. Review Procedures and Criteria
VI. Method of Applying
VII. Inquiries

This program is described in the Catalog of Federal Domestic Assistance No. 13.393, Cancer Cause and Prevention Research and No. 13.856, Microbiology and Infectious Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended; 42 USC 282) and administered under PHS grant policies and Federal Regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

I. BACKGROUND INFORMATION

The Division of Cancer Cause and Prevention (DCCP) of the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID) invite applications for Cooperative Agreements to support research projects into the microbiological etiology of Acquired Immune Deficiency Syndrome (AIDS) in humans. This is a new disease which was first reported in 1981 in homosexual males. The syndrome is characterized by severe immunosuppression, an associated outbreak of Kaposi's sarcoma and lymphomas, and/or a variety of opportunistic infections. The immunological status is commonly characterized by lymphopenia, cutaneous anergy, reduced helper T-lymphocyte subpopulations, and inversion of the helper/suppressor T-lymphocyte ratio. In addition, affected individuals may often have a prodrome of chronic fever, weight loss, diarrhea, and lymphadenopathy. Among affected subjects there is frequent evidence of infection with multiple viruses. AIDS patients now include both homosexual and bisexual males, heterosexual intravenous drug users, hemophiliacs, Haitians and some infants. In addition to disorders of immunological function, approximately half of the AIDS victims suffer from Pneumocystis carinii pneumonia and about one-third have Kaposi's sarcoma (KS) or lymphomas. The mortality rate is near forty percent overall, but closer to eighty-five percent for cases diagnosed early in 1981. The long-term prognosis for AIDS is very poor.

The recent involvement of hemophiliacs, apparently normal children, and some common epidemiological features now suggest a blood-borne, venereal, or close-contact transmissible biological agent as the causative factor. Two viruses, human cytomegalovirus (HCMV) and Epstein-Barr virus (EBV), have already been linked with AIDS, KS, and lymphomas. HCMV has been associated with KS by at least one molecularly oriented study of KS tissue, and EBV determined nuclear antigen has been demonstrated in tissues of several AIDS patients with a Burkitt's-like lymphoma. Further, several viruses have already been associated with certain human cancers: the etiological association of EBV with nasopharyngeal carcinoma; the papilloma viruses with malignancies of the skin, cervix and anus; HCMV with KS; and human T-cell leukemia-lymphoma virus (HTLV) with several malignancies. Recent advances in the study of cellular and viral oncogenes relative to cancer induction appear promising in ferreting out a basic mechanism of cancer induction. All these advances indicate that there is a rational basis for initiating systematic efforts to search for the transmissible agent presumed responsible for the AIDS syndrome and Kaposi's sarcoma.

II. RESEARCH GOALS AND SCOPE

A. Scope

The purpose of this RFA is to stimulate studies aimed at a direct microbiological approach to the problem. It is designed to encourage studies on the search for the isolation, and the characterization of the biological agent(s) which may be the primary causative factor(s) in AIDS and KS. The studies proposed should encompass not only the classical microbiological technologies for isolation and characterization of the agent, but also the contemporary technologies of immunology, cytogenetics, and molecular biology. Since HCMV and EBV, both transforming viruses, have been implicated in immune suppression and in association with KS and lymphomas, definitive studies of HCMV and EBV in terms of their relationship to the etiology of AIDS and KS would be considered as pertinent to the objectives of the RFA. However, it is emphasized that projects involving either or both RNA-core or DNA-core viruses, bacteria, rickettsia, or other potentially causative agents will be considered. Examples of the types of studies that might be appropriate include:

1. Direct in vivo and in vitro efforts at isolation, identification, and characterization of the causative biological agent.

2. Analysis of human tissue with appropriate tests indicative of the presence, state of integration, and location of viral or pro-viral DNA, or other infectious forms.

3. Recognition and identification of marker antigens of pathognomonic significance.

4. Cytogenetic analysis for chromosomal changes that relate to disease induction.

5. In vitro search for direct morphological transformation and/or cytopathology of appropriate target cells.

The NCI/NIAID plan at least annual meetings of collaborating investigators funded under this RFA ("working group"). Collaborating investigators may constitute an independent working group or may become part of an already established AIDS working group. These annual or more frequent meetings of the working group will provide an opportunity for the development of collaborative arrangements between investigators performing complementary research. At this time it is impossible to explicitly outline the nature of such arrangements since the scope of projects to be funded is unknown. Typical arrangements may include the exchange of selected reagents, the exchange of certain human specimens, and/or the exchange of current information. The NCI/NIAID will require these types of exchange and will attempt to facilitate them. This cooperation will hasten the resolution of the important questions relevant to this epidemic and will result in a more effective allocation of funds. It is anticipated that NCI/NIAID staff will play a key role in coordinating and facilitating such collaborations as various research activities evolve by identifying data points, comparing protocols, comparing results, etc. Additional details of this involvement are outlined below under "Terms of Award."

B. Safety

Because of the unknown nature of the disease, investigators will be required to utilize appropriate laboratory control measures. Procedures should be used representative of good microbiological techniques applicable to the handling of materials containing hepatitis B virus or other infectious agents which may be transmitted by ingestion, parenteral inoculation, or exposure of mucous membranes to infectious droplets. As an additional precaution, it may be advisable to use a biological safety cabinet. See also V.C.4. for a reference to recommended procedures and precautions.

III. MECHANISM OF SUPPORT

Awards will be made as Cooperative Agreements. These are assistance relationships involving substantial involvement with NCI/NIAID staff, as outlined under Part IV, "Terms of Award." NCI/NIAID anticipate making multiple awards as a result of this request. Up to $2,000,000 ($1,000,000 by NCI and $1,000 000 by NIAID) will be allocated to fund the initial year's awards for meritorious applications. Awards will be made for project periods of up to five years. All policies and requirements which govern the grant programs of the PHS apply, including the requirement for cost sharing.

IV. NATURE OF INVOLVEMENT OF NCI/NIAID STAFF: TERMS OF AWARD

This section outlines the interactions between recipients of these cooperative agreements and NCI/NIAID program staff.

1. The awardees shall develop research protocols and plans in accord with their individual interests and strengths as well as the minimum requirements included in these terms of award.

2. The NCI/NIAID staff will serve as a resource of information on the activities of various members of the working group and will act to facilitate collaboration among involved researchers. It is in the context of the Working Group meetings that the awardees, with the assistance of NCI/NIAID staff, will identify and develop these collaborative areas. It is anticipated that there will be exchange of selected reagents, exchange of certain human specimens, and/or exchange of current information and that NCI/NIAID staff will facilitate interaction by identifying data points, comparing protocols, and comparing results.

V. REVIEW PROCEDURES AND CRITERIA

A. Assignment of Applications

Applications will be received by the NIH Division of Research Grants (DRG) and referred to the same Initial Review Group for scientific merit review. NIH referral guidelines generally will apply, and DRG will work with both NCI and NIAID for assignment of the grant applications.

B. Review Procedures

All applications submitted in response to this RFA will be reviewed in competition with each other by:

1. An NIH peer review group and

2. The National Cancer Advisory Board and/or the National Advisory Allergy and Infectious Diseases Council

C. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals (see II. RESEARCH

GOALS AND SCOPE). If the application is judged by the NIH to be unresponsive, it will be returned to the applicant.

The factors considered in evaluating applications in response to this RFA will be:

1. Scientific merit of research approach, design, and methodology.

2. Research experience and competence of the Principal Investigator and staff to conduct the proposed studies.

3. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.

4. Adequacy of existing/proposed facilities and resources. This includes adequacy of patient resources to ensure completion of meaningful studies in a reasonable period of time. Additionally, the facilities used for these studies must be suitable to permit appropriate laboratory control measures for agents equivalent to hepatitis B virus. Facilities and laboratory practices must be consistent with the following reference: CDC Morbidity and Mortality Weekly Report, Vol. 31, No. 43, November 5, 1982.

5. Scientific, technical or medical significance and originality of proposed research.

6. Reasonableness of proposed costs.

VI. METHOD OF APPLYING

A. Format of Applications

1. Applications must be submitted on form PHS 398 (Rev. 5/82), the application form for research grants. Application kits are available at most institutional business offices, or may be obtained from the DRG, NIH. The format and detail applicable to regular research grant applications should be followed and the requirements specified under Review Criteria (V.C.) must be fulfilled. Since NCI/NIAID plan at least an annual meeting of the Working Group, applicants are encouraged to include in their budget travel funds for the principal investigator to attend at least one meeting per year in Bethesda, Maryland.

2. The number and title of this RFA should be typed in section 2 on the front page of the grant application form.

B. Application Procedure

1. The completed original application and six (6) exact copies should be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

an additional one (1) copy should be sent to:

Dr. Jack Gruber
Acting Chief
Biological Carcinogenesis Branch, DCCP
National Cancer Institute
National Institutes of Health
Landow Building - Room 9A22
Bethesda, Maryland 20205

Telephone: (301) 496-9740

an additional copy should be sent to:

Dr. William P. Allen
Virology Program Officer
BVB/MIDP
National Institute of Allergy and
Infectious Diseases
Westwood Building - Room 736
Bethesda, Maryland 20205

Telephone: (301) 496-7453

and one copy of the application should also be sent to:

Dr. Harold Waters
Division of Research Grants
National Institutes of Health
Westwood Building - Room 2A16
Bethesda, Maryland 20205

C. To ensure their review, applications should be received by August 1, 1983. This is a one-time request for applications. NCI/NIAID have no plans to reissue this announcement at any future date. Applications received after the above date will be considered unresponsive and will be returned without review. The DRG will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VII. INQUIRIES

Inquiries may be directed to:

Dr. Jack Gruber
Biological Carcinogenesis Branch
National Cancer Institute

or to

Dr. William P. Allen
Bacteriology-Virology Branch
National Institute of Allergy and
Infectious Diseases

at the above addresses.

ANNOUNCEMENT

REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

NIH-NCI-DRCCA-CPB 83-1

THE ROLE OF MICRO AND MACRONUTRIENTS IN THE PREVENTION OF CANCER

NATIONAL CANCER INSTITUTE

Letter of Intent Receipt Date: July 1, 1983
Application Receipt Date: August 1, 1983

The Division of Resources, Centers, and Community Activities (DRCCA), National Cancer Institute (NCI), invites applications for cooperative agreements to support risk reduction clinical trials which are directed at examining the role of micro and macronutrients in the prevention of cancer.

The proposed studies should seek to elucidate further the protective effects of inhibitors or of dietary prescriptions in reducing the incidence of cancers of specific sites.

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. As more fully described later in this announcement, the recipients will have primary responsibility for the development and performance of the activity. However, there will be government involvement with regard to (1) securing an Investigational New Drug (IND) approval from the Food and Drug Administration (FDA), (2) monitoring of safety and toxicity and, (3) coordination and assistance in obtaining the chemopreventive agent.

This RFA solicitation represents a single competition, with a specified deadline of August 1, 1983, for receipt of applications. All applications received in response to the RFA will be reviewed by the same National Institutes of Health (NIH) Initial Review Group (IRG).

Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

This program is described in the Catalog of Federal Domestic Assistance No. 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

I. BACKGROUND

Epidemiologic studies and laboratory research results support the concept that the incidence of cancer may be influenced by the levels of various nutrients and non-nutritive substances in the diet. A number of natural micronutrients including vitamin C, beta carotene, vitamin A or its analogs, selenium and alpha tocopherol have been associated, in animals or test systems, with the inhibition of carcinogenesis or have been associated with reduced cancer incidence, in epidemiological investigations.

The level of dietary fat has shown a positive correlation with incidence of cancer of several sites while increased fiber intakes has shown a negative correlation with the incidence of cancer at several sites. A number of mechanisms have been postulated including increased detoxification of carcinogens, alteration of metabolism by decreased activation, scavenging of the active molecular species, prevention of the carcinogenic agent from reaching the critical target in the cell, altering permeability or transport, and competitive inhibition. Other possible mechanisms include antagonism of promoting agents or induction of differentiation of malignant cells.

Because of the numerous reports concerning the effectiveness of dietary manipulation or the administration of certain compounds in interfering with carcinogenesis in animals and the many epidemiological studies suggesting a possible negative association of certain dietary factors with cancer incidence, clinical intervention studies are now encouraged.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing and implementing randomized controlled clinical trials to study the effect of micro- or macronutrients on cancer risks in humans. Micronutrients include, but are not limited to the following: beta carotene, vitamin A or analogs, vitamin C, selenium and alpha tocopherol. In addition, intervention trials involving several macronutrients including fats, vegetables, fruits, cereals and fibers will be considered.

This RFA is limited to clinical trials but excludes focus on skin cancer as the study end-point with the exception of melanoma.

The studies of interest are risk reduction clinical trials involving (a) normal populations, (b) populations known to be at increased risk but free of neoplasia, or (c) high risk populations with identified precursor or pre-cancerous lesions. These studies would require the administration of the designated inhibitors or dietary prescriptions in a randomized study with follow-up to determine the effects. Proposals involving studies of populations already having neoplastic lesions are not acceptable within the scope of this RFA.

Several items with regard to the proposal itself are provided as follows:

1. The applicant is encouraged, wherever germane, to focus attention on a specific target group, or to identify a source of participants and to

address the methodological, organizational, and theoretical issues in a detailed manner.

2. The applicant should provide a description of the target population or group chosen and should justify the selection of this group. The group should be defined, where appropriate, by age, sex, race, socioeconomic status, dietary customs, education, geographic location, occupational or life style risk factors, and relevancy to a specific cancer problem and to its possible prevention by designated inhibitors or dietary manipulations.

3. The applicant should specify the methods to be used to document nutrient intake at baseline and adherence to the prescribed intervention during the course of the trial.

4. The applicant should clearly indicate the clinical chemistry and biologic aspects of the study to include collection, storage, handling and analysis of biological samples. The methods and equipment to be utilized and the technical qualifications and experience of the personnel involved must be addressed.

5. The applicant should elucidate any known or potential safety or toxicity considerations, the techniques and procedures for monitoring and reporting any adverse health effects and appropriate dose modifications based on toxicity monitoring.

6. The applicant must indicate his agreement to work cooperatively with NCI staff in the implementation and conduct of the study.

III. MECHANISM OF SUPPORT

Awards will be made as Cooperative Agreements. These are assistance relationships involving cooperation with NCI staff, as outlined under Part IV, "Terms of Award." The planning, direction and execution of the proposed research will be the responsibility of the applicant with assistance from the NCI staff. The total project period for applications submitted in response to this RFA should not exceed five years. The intent is to fund projects of high scientific merit, with total costs amounting to $3 million per year. This level of activity is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

The awardees will develop a proposal based on their past experience, research interests, and information generated through pilot projects. The protocol shall be clearly written, well documented and appropriately annotated for background, objectives, eligibility criteria, treatment administration, statistical considerations and quality control.

A copy of the format which should be followed in the development of the proposal is available from the Program Director, listed in VII.

IV. NATURE OF COLLABORATION AND ASSISTANCE FROM THE NCI STAFF: TERMS OF AWARD

This section outlines the collaboration between recipients and NCI program staff.

A. Safety and Toxicity Review

Safety and toxicity aspects of the peer reviewed, approved, high priority proposals will be reviewed by an NCI staff committee chaired by the Associate Director, Prevention Program, DRCCA, NCI, or his designee. The primary purposes of this review are: (1) to insure that safety and toxicity issues have been addressed, and (2) to assure that the proposed research is in compliance with all FDA requirements and approvals. The NCI staff will follow up on these recommendations to ensure adequate safety and compliance.

B. Quality Control and Adverse Reaction Reporting

1. The awardees are expected to set up mechanisms for quality control. Quality control will require some or all of the following as relevant: compliance with protocol requirements for eligibility, treatment and follow-up; laboratory data; dietary data; pathological materials; and operative reports.

2. For chemopreventive agents, investigators are required to conform to NCI guidelines for use of investigational drugs including investigator registration (Form 1573), maintaining a record of drug receipt and reporting of adverse drug reactions. Life threatening or unexpected toxicity must be reported by the investigator immediately by telephone to NCI and confirmed with details in writing within two weeks. The investigator will be responsible for amending protocols and consent forms based on new toxicity information sent to the investigators by NCI staff. The NCI staff has developed mechanisms for prompt reporting to other investigators of all unexpected or serious toxicity caused by IND agents.

3. NCI staff is responsible for assuring the adequacy of safety monitoring and quality control for all chemopreventive studies involving NCI-sponsored IND drugs. The NCI staff will review the mechanism established by each applicant for quality control of clinical studies. These mechanisms must conform with FDA regulations.

   NCI is establishing a clinical chemistry quality assurance program which will provide guidance in the quality control of selected laboratory determinations. Each applicant will be expected to participate in the laboratory quality control activity if applicable.

C. Data Management and Reporting Requirements

1. Data acquisition and analysis is the responsibility of the investigator. Data which must be collected are listed in the protocol format available from the Program Director; see section VII. Investigators will be required to submit reports to NCI using the following schedule and format:

a. Semiannual Reports

Semiannual scientific reports should report on the progress of the project during the previous six months and the cumulative progress of the study.

The semiannual report should include:

(1) A concise narrative progress summary covering the previous six months (give dates of the six-month period utilized) and the cumulative progress of the study.

(2) Tabular displays of:

(a) Accrual history of the project generally broken down in six-month periods. In additon to total accrual, report number ineligible, number inevaluable, and number of study violations.

(b) Interim analyses of results, if appropriate.

(c) Toxicities, graded as to severity.

(3) Provide explanations in case of any of the following: increase or decrease in accrual, any unusual or unexpected incidence of ineligible or inevaluable participants, or any unusual or unexpected study violations.

(4) Brief descriptions of quality control measures such as review of records, on-site monitoring, biochemical monitoring of study compliance, etc.

(5) A list of all publications related to work under this cooperative agreement. This listing should include published references, manuscripts in press or submitted. Submit two copies of each reprint.

(6) Curriculum vitae will be provided if there has been a requested change in any of the project investigators.

b. Annual Report

An annual expenditure report and budget for the forthcoming 12-month period shall be submitted at least two months prior to the funding anniversary using standard NIH formats.

c. Final Study Report

The final report of a completed study shall consist of detailed analyses of results and toxicity, plans for publications, a comprehensive list of all previous publications related to this project, and plans for archiving and storing the study records.

2. The NCI staff will have access to the data for reviewing toxicity and safety, preparing NDA applications and for any monitoring required by other Federal agencies. The data generated, however, is the property of the awardee institution. NCI staff may encourage and facilitate sharing of data between investigators when this is in the mutual interests of the investigators and NCI.

D. Investigational New Drug (IND)

The NCI will have the option to cross file or independently file an IND on investigational drugs evaluated in trials supported under the cooperative agreements.

NCI will advise investigators of specific requirements and changes in requirements concerning investigational drug management for compliance with NCI and the FDA guidelines and regulations. Investigators performing trials under cooperative agreements will be expected, in cooperation with the NCI, to comply with all FDA monitoring and reporting requirements for investigational agents, for reporting adverse reactions, and for maintaining necessary records of drug receipt, use, and distribution.

Approval by the Institutional Review Board (IRB) must be obtained by awardees on all protocols because of the involvement of human subjects.

Informed Consent Forms must comply with NIH guidelines and should include preclinical and clinical toxicology information as relevant.

Awardees will be responsible for amending Informed Consent Forms if new toxicity information becomes available.

V. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Each application submitted in response to the RFA will be reviewed by: (1) an appropriate review panel of the NIH, (2) a DRCCA safety review and (3) the National Cancer Advisory Board at its regularly scheduled quarterly meeting which reviews grants after the initial review.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals, and fall within one or more of the specified research categories (see II. OBJECTIVES AND SCOPE). If the application is judged by the NCI to be not responsive, the applicant will have the opportunity of having the application considered along with other unsolicited proposals received by the NIH in the review cycle which is current at that time.

The factors considered in evaluating the scientific merit of each response to this RFA will be:

1. Scientific merit of the research approach, design, and methodology to include considerations of toxicity, safety and quality assurance of the research.

2. Scientific, technical, or medical significance and originality of the proposed research.

3. Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.

4. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.

5. Relevancy and appropriateness of the specific target population along with assurance as to their accessibility.

6. Identity of sources of data, tissues, fluids, etc., procedures for their analysis and assurances as to their accessibility.

7. Accessibility of the inhibitory or other agents. If an IND is held for the agent, that information should be furnished at the time of proposal submission. If the NCI is to assist in obtaining the IND, that information should be furnished.

8. Reasonableness of the proposed budget and duration.

VI. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to contact program staff by telephone or to submit a one-page letter of intent which includes a very brief synopsis of proposed areas of research and identification of any other participating institutions. This telephone contact or letter of intent should be addressed to Dr. W. Malone at the address located under VII. The Institute requests such contact to provide an indication of the number and the scope of applications to be received and for the purposes of identification of overlap and/or redundancy with currently funded research. The letter of intent is not binding; it will not enter into the review of any proposal subsequently submitted, nor is it a mandatory requirement for the submission of the application.

B. Format of Application

Applications must be submitted on Form PHS 398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the Division of Research Grants (DRG), NIH. The conventional presentation format and details applicable to regular research grant applications should be followed, and the requirements specified under Review Criteria (see section V.B.) must be fulfilled. The words "PROPOSAL IN RESPONSE TO RFA NIH-NCI-DRCCA STUDIES TO EXAMINE THE ROLE OF MICRO AND MACRONUTRIENTS IN THE PREVENTION OF CANCER," must be typed in section 2 of the face page of the application.

C. Application Procedures

The completed original application and six (6) copies should be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

To ensure their review, applications should be received by August 1, 1983. Applications received afte that date will not be considered under this RFA. A copy of the application should also be sent to Dr. Malone at the address shown below.

VII. INQUIRIES

Inquiries may be directed to:

Winfred F. Malone, Ph.D., M.P.H.
Chemoprevention Branch
Blair Builing - Room 624
National Cancer Institute
Bethesda, Maryland 20205

Telephone: (301) 427-8648

ANNOUNCEMENT

NATIONAL CANCER INSTITUTE

The National Cancer Institute (NCI) invites applications for National Research Service Award Act research training grants, individual postdoctoral fellowships and senior postdoctoral fellowships in all the basic and applied sciences relevant to cancer. Research training grants may support both predoctoral and postdoctoral trainees. Applications proposing quality research training in the following areas will be of special interest to the NCI.

Surgical Oncology - Postdoctoral research training for physicians in the basic or applied sciences.

Radiation Oncology - Postdoctoral research training for physicians in the basic or applied sciences.

Preventive Oncology - Predoctoral and postdoctoral research training in the following areas:

1. cancer control science;
2. endogenous and exogenous carcinogens;
3. mechanisms of carcinogenesis;
4. genetics of cancer susceptibility and resistance;
5. cancer epidemiology and biostatistics
6. interruption and/or reversal of carcinogenesis;
7. protection from exposure to carcinogens or protection from their effects;
8. chemoprevention;
9. cancer-related nutrition;
10. behavioral sciences as they relate to prevention oncology;
11. immunoprevention;
12. risk factor modification.

Inquiries should be addressed to:

Barney Lepovetsky, Ph.D., J.D.
Chief, Cancer Training Branch
Division of Resources, Centers and
Community Activities
National Cancer Institute
National Institutes of Health
Blair Building - Room 717
Bethesda, Maryland 20205

Telephone: (301) 427-8898

ANNOUNCEMENT

CELLULAR AGING RESEARCH: DIFFERENTIATED CELLS IN CULTURE

NATIONAL INSTITUTE ON AGING

Application Receipt Dates: July 1, November 1, March 1

I. INTRODUCTION

The National Institute on Aging (NIA) was established in 1974, to conduct and support biomedical, behavioral and social research and training related to the aging process and the diseases and other special problems and needs of the aged. Consistent with this mandate, Cellular Biology, a subprogram of the Molecular and Cellular Biology Program, supports research on mechanisms of cellular aging with the use of cell culture technologies. The purpose of this announcement is to encourage further research and training activities in cellular aging utilizing tissue and organ specific cells in culture.

II. BACKGROUND

Cellular events are probably major determinants of longevity and senescence. The study of cells as they "age" in culture and of cells derived from humans and experimental animals of various ages permits investigation of cellular events consequent to aging independent of the complexity of the whole organism. To date most such studies have used fibroblast-like cells of dermal and lung origin, these being easily obtained and cultured. Although such cells have yielded valuable information on various aspects of in vitro cellular aging, and on cellular and molecular biology in general, these systems have not yet been sufficiently characterized with respect to cell heterogeneity in mass cultures, in vivo precursors of in vitro cultures, and specific functional markers that can be compared with those of cells in vivo. The NIA earlier issued an announcement inviting applications addressing these questions (NIH Guide for Grants and Contracts, Vol. 9, No. 2, January 25, 1980).

Because of recent advances in cell-culture technologies, an increasing number of differentiated cells in culture are likely to be available for comparative studies of cellular aging. Recognizing that phenotypic, and perhaps genotypic, differences exist between cells in vitro and in vivo, nonetheless many differentiated cells do express known functional traits when maintained in culture. Several differentiated

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This program is described in the Catalog of Federal Domestic Assistance No. 13.866, Aging Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74, and section 472, 42 USC 2891-1, and administered under Federal Regulations 42 CFR Part 66.

cell lines also exhibit limited in vitro proliferative capacity, as do fibroblast-like cells. Additional information regarding differentiated cells in culture may be obtained from the following references:

> Jacoby, W. and I. Pastan (eds.). 1979. Methods in Enzymology. Cell Culture. L VIII, Section III, Academic Press.
>
> Montagna, W., A.M. Kligman, K.W. Wuepper and J.P. Bentley (eds.). 1979. Proceedings of the 28th Symposium on the Biology of Skin. J.Invest. Dermatol. (special issue on aging):73.
>
> Nichols, W.W. and D.G. Murphy (eds.). Differentiated Cells in Aging Research. Internat. Rev. Cytol. Supplement, 10.
>
> Harris, C.C., B.S. Trump and G.D. Stoner (eds.). 1980. Cultured Human Tissues and Cells in Biomedical Reserch. Methods in Cell Biology, Volume 21, Parts A and B, Academic Press.

III. GOALS AND SCOPE

The goal of this announcement is to encourage research on the mechanisms of cellular aging. The use of differentiated cells in culture provides an excellent opportunity to study age-associated alterations in differentiated functions that are expressed by cells in vitro. Such studies could lead to an understanding of mechanisms of age-related functional decline in various tissues and organs.

IV. SPECIFIC OBJECTIVES

The NIA seeks research and research training grant applications in cellular aging, encompassing growth and nutrition, somatic cell genetics and various aspects of cellular, molecular and developmental biology pertaining to differentiated cells. Research is encouraged in, but not limited to, the following areas:

1. Age-related changes in structure and function of differentiated products (specific structural proteins and enzymes) and other biochemical properties of primary and secondary cultures.

2. Age-related changes in membrane structure and function affecting: inter- and intra-cellular communication; energy production; and antigenic, absorptive, receptor and other properties of the cell surface.

3. Age-related alterations in subcellular structures involved in motility, digestion, detoxification, secretion, and various synthetic functions of the cell.

4. Age-related changes in nuclear structure and function (e.g., chromatic structure; DNA replication and repair; regulation of gene expression; ribosome production; nuclear-cytoplasmic interactions; chromosomal abberrations and neoplastic transformation).

5. The relationship between in vitro and in vivo cellular aging as elucidated by cell and tissue transplantation and the use of chimeric and genetic mosaic animals.

6. The use of somatic cell genetics to understand the genetic basis of cellular aging and regulatory mechanisms of cellular growth relevant to the aging process.

7. The development of new strains of cells more differentiated than fibroblasts; this is especially important for human strains. Examples are human uterine smooth muscle cells and human aortic smooth muscle cells.

8. The requirements for establishment of normal differentiated cell strains capable of expressing differentiated traits (e.g., nutrition, growth factors, feeder layer, co-cultivation and other environmental conditions, such as oxygen tension, which affect culture growth) and perturbations or procedures that alter, inhibit or delay age-related changes in differentiated functions.

Although studies with cultured human cells (e.g., cells obtained from vascular and nervous tissues, gastrointestinal and urinary tracts, endocrine and exocrine organs, retina, lung, bone, muscle and skin) expressing tissue and organ specific functions are preferred, use of other vertebrate cell systems, including embryonic cells, may be desirable in some cases. The NIA maintains colonies of laboratory mice and rats of different ages. Applicants interested in using these animals must contact, prior to submitting applications:

Chief, Molecular and Cellular Biology Branch
Building 31 - Room 5C19
National Institute on Aging
Bethesda, Maryland 20205

Telephone: (301) 496-6402

To support research on cellular aging, the NIA has established, under contracts, an Aging Cell Repository. Additional information on these resources may be obtained from publications by N.K. Das and D.G. Murphy on the National Institute on Aging Cell Repository, (Exp. Aging Res. 4:321-331. 1978), available upon request from the Molecular and Cellular Biology Branch.

V. MECHANISMS OF RESEARCH AND RESEARCH TRAINING SUPPORT

The primary mechanisms for support of this program are:

1. Project Grant (the traditional NIH research support mechanism).
2. Postdoctoral Fellowship (the Individual National Research Service Award).

Additional mechanisms for support are:

3. Program Project Grant* (for multidisciplinary research involving several projects with a common focus).

4. New Investigator Research Award** (an optional, introductory grant mechanism; applicants may not have previously been supported as Principal Investigators by a U.S. Public Health Service research grant; ceiling $30,000 per year for three years).

5. Clinical Investigator Award** (for clinically trained investigators; three years of support: salary up to $30,000; supplies etc. up to $10,000 annually).

6. Research Career Development Award

7. Institutional Training Grant* (Institutional National Research Service Award).

* Potential Applicants should contact NIA staff.
** Write NIA (see below) for information and instructions.

VI. REVIEW PROCEDURES AND FUNDING POLICY

According to standard referral guidelines, the NIH Division of Research Grants will assign all applications to appropriate NIH study sections for initial scientific merit review and to an appropriate Institute or Division for final review by its National Advisory Council/Board. Applications submitted in response to this announcement will compete with all NIA grant applications for funding consideration. No set-aside money is available for these applications.

VII. METHOD OF APPLYING

Use the appropriate NIH research or research training grant application kits. If your institution does not have them, copies may be obtained by writing:

Office of Grant Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7441

Please type the phrase NIA CELL BIOLOGY PROGRAM on the face page of the application. Enclose a cover letter indicating that the application is in response to this announcement.

Forward application to:

Division of Research Grants
National Institutes of Health
Westwood Builing - Room 449
5333 Westbard Avenue
Bethesda, Maryland 20205

Application receipt dates for Research Project Grants and Special Research Awards are: July 1, November 1 and March 1.

Receipt dates for applications for individual or institutional National Research Service Awards, Program Project Grants, Clinical Investigator Awards, and Research Career Development Awards are: June 1, October 1 and February 1.

Prior to formal submission of an application, please send a letter of intent to the Cell Biology Program (see address below). Include name of principal investigator, institutional address, title of application, and abstract of proposed research.

VIII. INQUIRIES AND CORRESPONDENCE

Inquiries and correspondence should be directed to:

Dr. DeWitt G. Hazzard
Head, Cell Biology Program
Biomedical Research and Clinical Medicine
National Institute on Aging
National Institutes of Health
Building 31 - Room 5C15
Bethesda, Maryland 20205

Telephone: (301) 496-6402

or

Dr. Richard L. Sprott
Chief, Molecular and Cellular Biology Branch
Biomedical Research and Clinical Medicine
National Institute on Aging
National Institutes of Health
Building 31 - Room 5C19
Bethesda, Maryland 20205

Telephone: (301) 496-6402

NOTICE

AVAILABILITY OF UPDATED GUIDELINES FOR COMPETING INSTITUTIONAL NRSA APPLICATIONS (T32) TO BE SUBMITTED TO THE NATIONAL EYE INSTITUTE

NATIONAL EYE INSTITUTE

At its January 1983 meeting, the National Advisory Eye Council made a number of recommendations with respect to the consideration and funding of institutional T32 awards by the National Eye Institute (NEI). These recommendations have been incorporated in updated guidelines for NEI applicants, which have been distributed to NEI institutional T32 program directors. Other interested parties may receive copies of the revised guidelines or further information by writing to:

Ronald G. Geller, Ph.D.
Associate Director
Extramural and Collaborative Programs
National Eye Institute
National Institutes of Health
Building 31, Room 6A03A
Bethesda, Maryland 20205

NOTICE

AVAILABILITY OF PRIMARY REFERENCE MATERIALS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The National Heart, Lung, and Blood Institute (NHLBI) will provide Primary Reference Materials to qualified investigators studying blood material interactions. Polyethylene and polydimethylsiloxane are available without charge in limited amounts for use as calibration standards for physicochemical and biological characterization of biomaterials for cardiovascular applications. Investigators should designate a reproducible material to be used as a routine control (secondary reference material) in all studies; the Primary Reference Material is to be used to calibrate the secondary reference material and thereby assess stability of experimental procedures. The Primary Reference Materials are available as sheets (2.5 x 7.5 cm) or tubing (4 mm ID, 5 mm OD, 0.5 to 1.5 m length) and are individually packaged, sterilized, and characterized.

To receive Primary Reference Materials, investigators should submit the following information in a letter: a brief description of experimental design which discusses how primary and secondary Reference Materials will be employed; polymer requested, including configuration and size; identification of the laboratory's secondary reference material; and details of the methods to be used for physicochemical and/or biological characterization of both the NHLBI Primary Reference Material and the laboratory's secondary reference material. This letter should also indicate a willingness to return the data obtained with the primary and secondary reference materials. Preferred characterization methods are discussed in Guidelines for Blood-Material Interactions (NIH Publ. No. 80-2185) and Guidelines for Physicochemical Characterization of Biomaterials (NIH Publ. No. 80-2186); these guidelines and additional information regarding methods by which the materials are characterized before delivery are available upon request. Please submit requests and inquiries to:

Devices and Technology Branch
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 312
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1586

NIH Guide
for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 12, No. 6, June 17, 1983

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(Continued)

The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

SITE VISITS TO ANIMAL CARE FACILITIES

NATIONAL INSTITUTES OF HEALTH

As announced in the February 25, 1983 NIH Guide for Grants and Contracts, the Office of Extramural Research and Training (OERT) is embarking on a series of site visits to awardee institutions to assess the adequacy of the NIH's current process for promoting proper care and use of animals in the biomedical research it funds. During January and February of this year, OERT developed a protocol for the visits and used it on three site visits to nearby institutions. The protocol includes meetings with top administrative officials, Animal Care Committee members, selected investigators and attending veterinarian(s) as well as tours of facilities. OERT is now ready to conduct site visits to ten awardee institutions to assess its current policies.

In order to assess the system presently used to ensure and promote animal welfare, OERT has randomly selected institutions which are not accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) but which submit annual assurance statements attesting to their observance of the principles set forth in the NIH's Guide for the Care and Use of Laboratory Animals. Ten institutions were selected: one was chosen from each of the ten Department of Health and Human Services'(DHHS) geographic regions, and three or four were taken from each of three categories of total annual NIH support of more than $10 million, $5-10 million, and less than $5 million. Using these criteria, OERT randomly selected the following institutions:

DHHS Region	Institution/Location
1	Brandeis University, Waltham, MA
2	New York University, New York, NY
3	Children's Hospital of Pittsburgh, Pittsburgh, PA
4	Bethune-Cookman College, Daytona Beach, FL
5	Northwestern University, Evanston, IL
6	University of Texas-Austin, Austin, TX
7	St. Louis University, St. Louis, MO
8	LDS Hospital, Salt Lake City, UT
9	Syntex Research Division, Palo Alto, CA
10	University of Washington, Seattle, WA

The ten institutions will be visited between June and September of this year by site visit teams composed of NIH employees and non-federal consultants. A member of the NIH staff will have notified the appropriate institutional representative(s) at least one month before the scheduled visit.

Additional information concerning this notice may be obtained from:

Dr. Louis R. Sibal
Office of Extramural Research and Training
National Institutes of Health
Shannon Building - Room 314
Bethesda, Maryland 20205

Telephone: (301) 496-4716

NOTICE

DELINQUENT LOAN RECIPIENTS

The Public Health Service (PHS), in collaboration with the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS), is engaged in an initiative intended to improve the management of debts incurred by recipients of Health Professions and Nursing Student Loans. As a first step, individuals employed by DHHS have been contacted and requested to make appropriate arrangements for repayment of delinquent loans.

A recent review of the National Institutes of Health (NIH) research data base showed that a small number of individuals who are currently principal investigators on NIH grants or contracts are delinquent on such loans, according to the records of the Health Resources and Human Services Administration, which administers the program.

The PHS expects that recipients of research funding will meet their obligations incurred as beneficiaries of PHS loan programs. The purpose of this notice is to encourage delinquent borrowers to contact the school that made the original loan and make appropriate arrangements for repayment.

NIH and PHS regret the circumstances that make this notice necessary, but trust that members of the research community recognize that these few individuals must adhere to the same standards as other recipients of student loans. To countenance delinquency--or even to appear to do so--surely would undermine public confidence in the stewardship of both PHS and the participating institutions.

NOTICE

NEW CANCER CONTROL GRANT GUIDELINES

DIVISION OF RESOURCES, CENTERS, AND COMMUNITY ACTIVITIES

NATIONAL CANCER INSTITUTE

The Division of Resources, Centers, and Community Activities (DRCCA), National Cancer Institute (NCI), expects to have revised grant guidelines available by June 15, 1983. These guidelines identify DRCCA's areas of programmatic interest for investigator-initiated research.

Copies of the guidelines will be available by writing to:

Chief, Cancer Control Applications Branch
Division of Resources, Centers, and
Community Activities
National Cancer Institute
Blair Building - Room 1A07
9000 Rockville Pike
Bethesda, Maryland 20205

ANNOUNCEMENT

SOCIAL AND BEHAVIORAL RESEARCH ON AGING

NATIONAL INSTITUTE ON AGING

I. BACKGROUND AND GOALS

The National Institute on Aging (NIA) continues to invite grant applications in its Behavioral Sciences Research (BSR) program. This program is concerned with the social, cultural, economic, and psychological factors that affect both the process of growing old and the place of older people in society. Research already shows the power of these factors; it shows that aging and the status of the elderly are not inevitably fixed but are subject to social modification and change. But more research is required on how these factors operate. In order to enhance the quality of life for older people and to contain the personal and social costs of health care and dependency, more knowledge is needed to strengthen the scientific basis for professional practice and public policy.

The BSR is one of the major extramural programs of the NIA. This Institute was established by law in 1974 for the "conduct and support of biomedical, social, and behavioral research and training related to the aging process and the diseases and other special problems and needs of the aged." Under this mandate BSR views health and well-being not narrowly within the framework of biological aging alone, but as the outcome of intricately interacting biological, psychological, social, and environmental processes. This program is coordinated with related programs on aging within NIA (e.g., in Biomedical Research and Clinical Medicine) and in such other organizations as the National Institute of Mental Health (NIMH), the National Institute of Child Health and Human Development (NICHD), and the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS).

This is not a one-time invitation for applications, but rather a standing call for research and training applications in the broad area of social and behavioral research in aging. More specific announcements are issued from time to time.

II. PROGRAM EMPHASES

Within this program four major emphases are applicable to most, but not all, research proposals: 1) The dynamic (rather than static) character of aging as a process and of social and historical change which affects the age structure of society and the ways in which individuals age. 2) The interrelatedness of old age with earlier ages, as later life

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This program is described in the Catalog of Federal Domestic Assistance No. 13.866, Aging Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under Federal Regulations 42 CFR Part 66. This program is not subject to A-96 Clearinghouse or Health Systems Agency review.

is interconnected with the full life course and older people are interdependent with other people of all ages. 3) The social and cultural variability of age and aging, both within a single society and across societies, as this variability reveals the nature and extent of cultural influences on the aging process, the lives of older people, and the general significance of age in society. 4) The multiple facets of age and aging, as social and psychological aging processes are in continuing interplay with biological and physiological aging.

III. PROGRAM CONTENT

Three broad, overlapping categories suggest the boundaries within which research is relevant to the Behavioral Sciences Research (BSR) program: 1) Older People and Society; 2) Biopsychological and Cognitive components of the aging process; and 3) Social Psychological Aging. The following outline indicates how these categories fit together into a comprehensive program. The scope of the program is illustrated by the topics listed, but is not limited to them. Research applications on a wide variety of related topics will be considered.[1]

1. Older People and Society refers to research on age as a structural feature of society, in the population, the organization of social roles and in social institutions. It includes studies of older people in the changing social and demographic structure of society as a whole as well as studies of how social structure influences behaviors, attitudes, and status of older people. Such studies lead to understanding of the conditions influencing the health and well-being of the elderly. Relevant research is currently conducted in such disciplines as sociology, anthropology, social psychology, history, economics, political science, geography, demography, and epidemiology.

    a. The subarea of age in the population is concerned with such topics as: Age composition of the population (implications for family structure, education, income maintenance programs, etc.); patterns of migration, rural-urban residence; and morbidity, mortality, causes of death.

    b. The second subarea of age-related societal structures emphasizes age as a structural feature of social systems and of social change. It includes research on, for example: Laws, expectations, and social norms; inequalities of income; differential opportunity for labor force participation, education; differential access to political opportunities (voting, office holding); environmental design (e.g., housing, communities, transportation systems); age-based conflict; age-integration vs. age-segregation; life-long education vs. age-based education; and social and cultural factors in health maintenance and functioning.

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[1] Given the expense associated with collecting original data, the employment of pre-existing data sets and their secondary analysis is encouraged, though in many instances the collection of new data may be required. The NIA and AoA have jointly sponsored the establishment of two data archives: 1) the National Archive for Computerized Data on Aging, ICPSR, University of Michigan, Ann Arbor, Michigan 48106, and 2) the Public Use Data Archive, Center for the Study of Aging, Duke University, Box 3003, Durham, North Carolina 27710. A wide variety of data sets of potential interest to researchers of aging may be obtained through these archives, which should be contacted directly for listings of their holdings. An Inventory of Longitudinal Studies of the Middle and Later Years is available through the Social Science Research Council, 605 Third Avenue, New York, New York 10016 or the Behavioral Sciences Research Program (BSRP) NIA.

c. The subarea of older people and social institutions refers to research on the relations of aging individuals to the several social institutions within which they grow old. It includes studies of the age structure of particular institutions, and of how institutions can shape older people's lives and can in turn be shaped by older people themselves. Systems for providing service to older people are included as examples of such institutions, although NIA emphasis is on scientific analysis of these systems generally rather than evaluation of specific services. Examples of topics falling within this subarea are: Family, household, and kin networks; friendships and peer groups; economic (e.g., firms, consumer organizations), religious, educational, political (e.g., age-based political movements), health, welfare, or leisure (e.g., recreational associations, retiree organizations) institutions. This subarea stresses the relation of such topics to changes in the society, for example to the effects of increasing age-grading, to reduced economic dependence of parents on adult children, to changes in mandatory retirement ages, and to rapid shifts in values than can result in estranging older cohorts from the dominant popular culture.

2. Biosychological and Cognitive Components of the Aging Process is concerned with the identification or specification of cognitive, intellectual, and perceptual changes and stablities that, interacting with biological processes, occur with aging. Such studies lead to understanding of the conditions under which perceptual and cognitive functioning are maintained into the middle and later years. Relevant research is currently conducted in such disciplines as neuroscience, behavioral genetics, psychology, anthropology, and sociology.

a. Biospychological Aging deals with the relationships between behavioral aging, on the one hand, and such aspects of physiological aging as constancy and change in neurological, immunological, and endocrine processes.

b. Cognitive Aging is concerned with age-related changes and stabilities in: Psychomotor skills (e.g., muscular strength, reaction time, complex tasks such as driving); perception and sensation (e.g., vision, audition, taste and smell, pain, touch, time perception); memory, learning, attention; cognition and intelligence; creativity and wisdom; and emotions and motivation.

3. Social Psychological Aging emphases the changes and stabilities with aging in the health, behavior, personality, and attitudes of people as related to the social environment. Studies in this category lead to understanding of the immediate social conditions under which physical health and psycholoical, social, and economic functioning are maintained into the middle and later years. A particular emphasis is placed upon longitudinal and cohort studies, including methodological and data-archiving projects.

a. Psychosocial Aging includes such components of the social psychological and social aging process as changes and stabilities in: Personality characteristics and processes; psychological coping mechanisms and styles; self-concept, self-esteem, and self-image; social psychological factors in motivation and performance; attitudes, beliefs, and values; interpersonal relationships over the life course (e.g., intimate relationships, isolation, loneliness, social influence and conformity, social exchange and equity, social support and networks, participation in social groups); role sequences and transitions: antecedents, consequences, and adaptations (e.g., life events, sequencing and timing of roles, role conflicts, death and dying, bereavement, retirement, and multiple or successive careers); socialization processes; and effective functioning and productivity.

b. Biosocial Aging and Health is concerned with how social and environmental processes, interacting with biological processes, influence health in the middle and later years: Interrelationships among health, attitudes, and behaviors; sociobehavioral mechanisms for health promotion and disease prevention; inter-play among work, health, and aging; and social, environmental, and technological factors associated with the need for and utilization of health-care services, including long-term care.

IV. MECHANISMS OF SUPPORT

The usual mechanisms are available for obtaining support for research and training. In addition, the NIA offers Small Grant Awards that provide one-year support for pilot and innovative research on selected topics (maximum of $15,000). Descriptions of mechanisms of support and any special guidelines for preparing applications are obtainable from NIA staff (VII. below).

V. METHOD OF APPLYING

Researchers considering submitting an application in response to this announcement are strongly encouraged to discuss their project with NIA staff in advance of formal submission. This can be done through a telephone conversation or through a written and brief (4-5 pages) research prospectus. Such discussions should take place at least two months before the submission of a formal application in order to allow sufficient time for BSR staff to provide consultation.

The appropriate NIH research or research training grant application kits can be obtained from your institution or from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7441

After you have completed the application, expedite its routing within NIH by:

- Printing and underlining NIA SOCIAL AND BEHAVIORAL RESEARCH on the upper margin of the face sheet.

- Checking the box on the application form indicating that your proposal is in response to this announcement.

- Enclosing a cover letter repeating tht this application is in response to this announcement of the NIA SOCIAL AND BEHAVIORAL RESEARCH.

Forward cover letter, application, and appropriate copies to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

Receipt dates for Research Project Grant and New Investigator Research Award applications are: July 1, November 1 and March 1; for all others (including Small Grants): June 1, October 1 and February 1.

VI. INQUIRIES AND CORRESPONDENCE

Correspondence, including requests for advice on further development of applications, will be directed to the appropriate project officer when mailed to:

Behavioral Sciences Research
National Institute on Aging
Building 31 - Room 4C35
Bethesda, Maryland 20205

Telephone: (301) 496-3136

ANNOUNCEMENT

HEALTH AND EFFECTIVE FUNCTIONING IN THE MIDDLE AND LATER YEARS

NATIONAL INSTITUTE ON AGING

I. INTRODUCTION

The National Institute on Aging (NIA) invites qualified researchers to submit grant applications for research projects designed to specify how psychosocial processes, interacting with biological processes, influence health and functioning in the middle and later years.

This announcement is part of the broad program of the Institute, which was established by law in 1974 for the "conduct and support of biomedical, social, and behavioral research and training related to the aging process and the diseases and other special problems and needs of the aged." Under this mandate, health and well-being are viewed, not narrowly within the framework of biological aging alone, but as the outcome of complex psychological, social, environmental, physiological, and medical processes. Four principles guiding NIA research are: (1) the dynamic character of aging as a process, and of social and historical changes which affect the age structure of society and the ways in which individuals age; (2) the interrelatedness of old age with earlier ages; (3) the social, cultural, and individual variability of age and aging; and (4) the continuing interplay between psychosocial and biomedical aging processes.

The special initiative[1] on health and effective functioning in the middle and later years is coordinated with related programs in other organizations including the National Institute of Child Health and Human Development (NICHD), the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), and the National Institute of Mental Health (NIMH).

II. BACKGROUND

The 20th century's triumph of extension of life means not only that the numbers of old people are increasing, but that more and more individuals can look forward to living out their lives to the full. As life expectancy has been extended, the proportion of adult life that might be spent in retirement has also been increased. However, it remains to be seen whether and how people will benefit from these added years. How can the relatively vigorous health, effective functioning, and productivity of the middle years be continued into the later years? How can disability and dependency be postponed until the last years of the extended life course?

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[1] See also page 5, this issue, for a description of broad goals, emphases, and content of the NIA program in behavioral sciences research.

Recent research findings are beginning to suggest how the productive middle years might be extended; how many disabilities of old age might be prevented or postponed; and how the costs of health care and dependency might be contained. For example, we now know that intellectual decline with aging (when it occurs) can often be slowed or reversed by relatively simple training interventions; that older people can often learn to compensate for declines in reaction time, memory, and other age-related deficits (e.g., through mnemonic strategies, carefulness, and persistence); that for the visual impairments suffered by many older people, particular styles and sizes of type can facilitate reading, and improved environmental design can offset inability to see large objects in low contrast; that for the serious malnutrition of many older people, food can be adapted to the age-related changes in taste and smell that influence eating behaviors; that health can be promoted through changes in smoking, diet, and exercise across the lifespan; that illness can often be alleviated through social supports and improved coping behaviors; that many serious disabilities (even when experienced in nursing homes) can be reduced by regimens that reward activity and independence.

We know that death is inevitable; but we also know in a most general sense, that biological, psychological, and social processes of growing old are to a considerable extent malleable. However, we need to specify the mechanisms and conditions that influence health and functioning during the middle and later years. NIA's goal in issuing this announcement is to encourage basic research studies of these mechanisms and conditions that can extend the productive middle years of life by preventing, postponing, or reversing current disabilities of old age.

This is not a one-time invitation for applications, but rather a standing call for research and training applications in the broad area of health and effective functioning in the middle and later years. More specific announcements will be issued from time to time.

III. SPECIFIC OBJECTIVES

The NIA seeks research grant applications for the study of specific mechanisms and conditions affecting particular aspects of health and functioning in the middle and later years of life. Such proposals will often require the formation of multidisciplinary research teams, given NIA's commitment to research on the linkages among behavioral, social, and biomedical processes.

Many researchable issues fall within the realm of health and effective functioning in the middle and later years. The following are offered as illustrations of appropriate topics.2/ Applications need not, however, be limited to these issues.

A. Work and Retirement

- Aspects of work situations that stimulate intellectual competence, provide incentives and opportunities for sustained or enhanced performance.
- Factors influencing vigor, intellectual functioning, memory and other physical and psychological capacities and motivations for continuing productivity and creativity.

2/ Accepted referral guidelines will be followed in assigning applications to NIA or to other Institutes.

- Processes and conditions associated with retirement that influence physical and mental functioning.
- Age-related disabilities specific to particular occupations; organizational and technological innovations to remedy or compensate for these deficits.

B. Health Institutions 3/

- Psychological and social factors that reduce the need for long-term care older people; alternatives to institutionalization.
- Influence of institutionalization on health and functioning of the institutionalized elderly and of their significant others (spouse, children, other relatives, friends).
- Psychosocial factors in the diagnosis and treatment of elderly by health-care practitioners.

C. Social Support

- Changes and stabilities in social networks as protections against disabilities in the middle and later years.
- Positive and negative consequences of social networks for health and functioning.

D. Health Behaviors and Attitudes

- Specific changes in life style or behavior that maintain health or prevent particular diseases.
- Age and/or cohort differences in health behaviors, attitudes, and beliefs.
- Ways of converting awareness of healthful practices into sistained behaviors.
- Ways of eliciting adherence to unpleasant therapies.
- Ways of coping with stress, ranging from "daily hassles" to life-threatening events.

3/ The NIA will support research that extends the knowledge base underlying the provision of health services for the aging and the aged. The NIA does not support demonstration, control, and evaluation projects. Services *per se* are not supported except in cases in which a service, or package of services, may be one of the experimental variables in a proposed study.

E. Personality

- Etiology and developmental course of disease-prone personality configurations over the life course (e.g., Type A vs. Type B behavior patterns).
- Individual differences in psychological and physiological response to chronic or persistent stressful situations.

F. Nutrition, Exercise, Sleep

- Psychosocial factors influencing age-related changes in food preferences, eating habits, and nutrition.
- Cohort differences in nutrition and consequences for health in the middle and later years of life.
- Long-term and short-term effects on health and effective functioning of various types of exercise.
- Psychosocial factors in etiology and therapies for age-related sleep disorders.
- Behavioral consequences of age-related sleep disorders.

G. Family and Household

- Psychosocial, physiological, and medical consequences of bereavement and the processes linking bereavement with health and functioning.
- Changes in household composition and resources and their interaction with health and functioning.
- Family and household decision-making, and patterns of intergenerational exchanges of material and emotional support, as they affect health and later-life development.

H. Methodological Studies

In addition to substantive topics, applications are sought for methodological projects which promise new understanding of the complex processes which influence health and effective functioning in the middle and later years.

- Improved longitudinal designs for examining the linkages between psychosocial and biomedical aging processes.
- Development of cohort-comparative, cross-cultural, and historical-comparative designs for examining the interrelationship between societal changes and variations in the individual aging process.
- Development of statistical and mathematical models of age-related behavioral changes that are suitable for the analysis of longitudinal and cohort-comparative data.

- Improved measures of health, productivity, and functioning, suitable for use in the field or in the laboratory.
- Development and improvement of measures of human performance and functioning suitable for tracing changes over the full life course.

IV. METHODOLOGY

While research applications need not be limited to any particular methodology of data collection or analysis, the use of objective, reliable, and valid measures of psychosocial, or biological health and performance is essential. Consideration should be given to the relative advantages and disadvantages of cross-sectional vs. longitudinal or cohort designs, or to the use of experimental and quasi-experimental designs in a variety of settings (including the laboratory, nursing home, health-care institution, residence, the community, and the workplace). Given the expense associated with collecting original data, the employment of pre-existing data sets and their secondary analysis is encouraged,4/ though in many instances collection of new data may be required to meet particular objectives.

V. MECHANISMS OF SUPPORT

The usual mechanisms of support for research and training are available, including the Small Grant Award (for one-year support for innovative and pilot research on selected topics; maximum of $15,000). Descriptions of these mechanisms are obtainable from NIA staff (VII. below).

VI. BACKGROUND READINGS - SELECTED EXAMPLES

D.S. Krantz, D.C. Glass, and N.E. Miller, "Behavior and Health" in the National Science Foundation, "Five-Year Outlook on Science and Technology," Vol. II, Washington, D.C.: U.S. Government Printing Office (NSF 81-41), November 1981, pp. 561-568.

Conferences on Epidemiology of Aging, DHEW Publication No. (NIH) 77-711 and NIH Publication No. 80-969.

D.L. Featherman, "The Life-Span Perspective," in the National Science Foundation, "Five-Year Outlook on Science and Technology,' Vol. II, Washington, D.C.: U.S. Government Printing Office (NSF 81-41), November 1981, pp. 621-648.

W.T. Bielby and R.M. Hauser, "Structural equation models." Annual Review of Sociology, 1977, 3, 137-161.

M.T. Hannan and B.B. Tuma, "Methods of temporal analysis." Annual Review of Sociology, 1979, 5, 303-328.

J.R. Nesselroade and P.B. Baltes (eds.), Longitudinal Research in the Study of Behavior and Development. N.Y.: Academic Press, 1979.

M.W. Riley, B.B. Hess, and K. Bond (eds.), Aging in Society: Selected Reviews of Recent Research. Hillsdale, N.J.: Erlbaum, 1983.

4/ NIA and AoA have jointly sponsored two archives: 1) the National Archive for Computerized Data on Aging, Inter-university Consortium for Political and Social Research, University of Michigan, Ann Arbor, Michigan 48106, and 2) Public Use Archive, Center for the Study of Aging, Duke University, Box 3003, Durham, NC 27710. An Inventory of Longitudinal Studies on the Middle and Later Years is available from the Social Science Research Council, 605 Third Avenue, N.Y., N.Y. 10016 or from Behavioral Sciences Research, NIA. Write directly to the archives for listings of their holdings.

VII. APPLICATION SUBMISSION AND REVIEW

Potential applicants are strongly encouraged to discuss their project with NIA staff in advance of formal submission. This can either be done through a telephone conversation or through a written and brief (4-5 pages) research prospectus.

Applicants should use the regular research project and program project grant application form (PHS 398), which is available at the applicant's institutional Application Control Office or from the following:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7441

In order to expedite the application's routing within NIH, Please (1) check the box on the application form's face sheet indicating that your proposal is in response to this announcement and print (next to the checked box) NIA HEALTH AND EFFECTIVE FUNCTIONING IN MIDDLE AND LATER YEARS, and (2) enclose a cover letter repeating that the application is in response to this announcement.

The cover letter and the completed application (along with six copies) should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

Receipt dates for Research Project Grant and New Investigator Research Award applications are: July 1, November 1, and March 1; for others, including Small Grants: June 1, October 1, and February 1.

Address requests for additional information, research prospectuses, and/or letters of intent to:

National Institute on Aging
Behavioral Sciences Research
Building 31C - Room 4C35
Bethesda, Maryland 20205

Telephone: (301) 496-3136

ANNOUNCEMENT

SOURCES SOUGHT FOR SMALL BUSINESS ORGANIZATIONS CAPABLE OF COMPETING FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM FUNDS TO DEVELOP REMOTE SPECTROMETRY FOR USE WITH GASTROINTESTINAL FIBEROPTIC ENDOSCOPY NIADDK-83-SS

NATTIONAL INSTITUTE OF ARTHRITIS, DIABETES, DIGESTIVE AND KIDNEY DISEASES

SOURCES SOUGHT: SMALL BUSINESS ORGANIZATIONS CAPABLE OF COMPETING FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM FUNDS TO DEVELOP REMOTE SPECTROMETRY FOR USE WITH FIBEROPTIC ENDOSCOPY IN RESEARCH, DIAGNOSIS AND TREATMENT OF DISEASES OF THE DIGESTIVE TRACT AND ASSOCIATED ORGANS. The Division of Digestive Diseases and Nutrition (DDDN), National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases (NIADDK), National Institutes of Health (NIH), is seeking organizations eligible to compete for grant support under the Small Business Innovation Research Program (SBIR) to create and develop through research remote spectrometry technology and devices for use with the fiberoptic endoscope, to measure physiological parameters *in situ* (1).

This is not a request for proposals or applications. This "Sources Sought" announcement is issued to determine the availability of organizations capable of performing the above described research and are interested in submitting an SBIR grant application to perform such research. The response to this inquiry will guide the NIADDK in a decision to release a request for applications or to determine other means to develop remote spectrometry technology for digestive diseases research.

BACKGROUND

Studies have shown the feasibility of measuring a variety of useful physiologic parameters using a detector placed at the end of a fiberoptic bundle. Investigators at the Oak Ridge National Laboratory have developed remote instrumentation for measuring the concentrations of plutonium and uranium in reprocessing solutions (2). Investigators in the Division of Research Services of the NIH have prepared a flexible, 0.4mm diameter fiberoptic pH probe which has been used to measure pH in the blood (3,4). There appears to be an opportunity for the further development, through research, for this type of technology to be used to measure many physiologic parameters of the digestive system in health and disease.

The potential for the application of fiberoptic remote spectrometry to the study of animal and human digestive diseases physiology and pathology should be developed. It is probable that substances, present in body fluids and known to induce color-indicator changes, could be measured. It is anticipated that such devices would have application in biomedical research, where endoscopy is emerging as a research tool, and in diagnostic and therapeutic procedures, where endoscopy is established.

REFERENCES

1. Small Business Innovation Research Program (SBIR); Small Business Innovation Development Act of 1982 (P.L. 97-219). NIH Guide for Grants and Contracts 11/(14):

2. Maugh T.H. Remote spectrometry with fiberoptics, Science 218:875-876, 1982.

3. Goldstein, S.R., J.I. Peterson, R.V. Fitzgerald. A miniature fiberoptic pH sensor for physiological use. J. Biomech. Eng. 102: 141-146, 1980.

4. Peterson, J.I., S.R. Goldstein, R.V. Fitzgerald, D.K. Buckhold. Fiberoptic probe for physiological use. Analyt. Chem. 52: 864-869, 1980.

INTERESTED ORGANIZATIONS

Please submit a letter of interest to the office named below, providing information on facilities and equipment available to perform remote spectrometry research, related organizational experience, and the qualifications and experience of key personnel.

Address replies and/or inquiries to:

Dr. Kirt Vener
National Institutes of Health
Westwood Building - Room 3A16
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7821

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA 83-3

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

MYCOLOGY RESEARCH UNITS

Application Receipt Date: October 14, 1983

I. BACKGROUND INFORMATION

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for program project grants to be initiated during FY 1984 for participation in an ongoing program of research in Mycology. NIAID is presently funding two Mycology Research Units (MRU), whose support terminates on August 31, 1984. In accordance with NIAID policy, program project proposals for Special Programs will now be received only at designated times. Support of new MRU or continuation of existing units will be on a competitive basis. We hope to fund at least two research units; however, the number awarded will depend upon the quality of the approved proposals. It is estimated that the direct costs for each of the research units will be approximately $250,000 per year.

Severe, sometimes life-threatening, systemic infections caused by fungal organisms have long been recognized in all age groups and in all parts of the U.S. Treatment of these infections now requires prolonged administration of relatively toxic drugs; this therapy may be ineffective even in the otherwise healthy patient. These infections are being recognized with increasing frequency as a major cause of both morbidity and mortality in patients with impaired immune defenses. Such patients as those with underlying disease who are undergoing immunosuppressive therapy, those with renal or other organ transplants, or severely debilitated patients, are all in a high risk group significantly subject to these severe systemic fungal infections. As the use of immunosuppressive therapies increases in the treatment of patients with malignant and immunologically mediated disease or with organ transplants, the frequency of systemic mycoses will undoubtedly increase as well and will continue to be a major health problem. Of particular concern are those increasing numbers of patients having the Aquired Immune Deficiency Syndrome (AIDS), many of whom are afflicted with life-threatening mycotic infections, especially severe candidal infections of oropharynx and esophagus.

This program is described in the Catalog of Federal Domestic Assistance No. 13.856, Microbiology and Infectious Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

Geographic distribution of primary fungal infections also plays a role in the epidemiology of some of these diseases; e.g., coccidioidomycoses are more prevalent in the dry southwestern U.S., while histoplasmosis infections are found most commonly in the more humid eastern and central U.S. The fungi of medical importance include, but are not limited to, Coccidioides immitis, Histoplasma capsulatum, Blastomyces dermatitides, Cryptococcus neoformans, Candida albicans, and Aspergillus fumigatus. Superficial infections of the skin caused by dermatophytes are of lesser significance as a major public health problem, but nevertheless merit imaginative new approaches in research. An active research program in mycology and related areas is of crucial importance to help resolve the serious public health problem of fungal disease.

Research in medical mycology also needs to be encouraged and stimulated because greater knowledge and understanding of these microorganisms will help resolve fundamental problems in microbiology and immunology. The questions asked when studying nonpathogenic microorganisms can also be directed to the pathogens. Contemporary approaches and sophisticated techniques currently used for fundamental investigations on nonpathogens (e.g., Saccharomyces) can also be applied to similar studies on pathogenic fungi. Modern methods in molecular biology, biochemistry, immunology, and genetics should be applied to this field as they have been so successfully applied to other fields of microbiology.

II. RESEARCH GOALS AND SCOPE

A. The NIAID proposes to maintain its program initiative in mycology and fungal disease research. The goal of this program is to increase knowledge of the biology of the causal microorganisms and of host-parasite interactions. This fundamental knowledge will then be applied to development and improvement of means of diagnosis, prevention, and therapy of these infections.

B. The NIAID wishes to develop multidisciplinary Mycology Research Units to serve as foci for research in fungal diseases. These units will be funded as program project grants. The areas of research emphasis for these program projects can be any or all of the categories listed in Item C. It is, however, desirable that a strong clinical component be made a part of any program project application. In addition, these programs will have certain characteristics distinguishing them from individual research grant proposals:

1. They will be based at a teaching hospital of a university or medical school, or at a medical school-affiliated hospital.

2. The program project will be multidisciplinary, combining the efforts of investigators in both clinical and basic science disciplines to focus on different facets of the overall problem of fungal infections.

3. Integration and coordination of different departments within an institution, or of different collaborating institutions, usually will be necessary for adequate program development.

4. The program project will consist of a number of individual subprojects, each with a clearly identified research task, and each with a principal investigator, staff, and budget.

5. The Program Director will be responsible for the overall direction and administration of the total project. It is expected that the principal investigators of each of the subprojects will act as members of a strong and coordinated research team, the whole directed toward resolving some of the many problems in fungal diseases. Translation of observations showing potential for clinical application should be considered as part of the research effort.

6. It is suggested that efforts be made to stimulate research in mycology and to make students more aware of the needs and opportunities in mycology research, at both the clinical and fundamental levels.

7. Only institutions with demonstrated expertise in both clinical and basic sciences, and with strong, ongoing research programs and resources that can focus on a multidisciplinary and multifaceted attack on fungal diseases will be considered for program project support under the provisions of this program.

C. The research interests in this program can focus on any or all of the following specific areas:

1. Biology of the causal organisms - growth, metabolism, genetics, chemical composition, antigenic structure, dimorphism, or phase variation of certain fungi;

2. Virulence factors of fungal agents;

3. Epidemiology of fungal disease and the causal agent;

4. The role of antibody and cell mediated immune responses in pathogenesis, recovery, and resistance;

5. Immunogens and immunopathology;

6. Pathogenesis and mechanisms of recovery and resistance;

7. Animal model systems;

8. Immunodiagnosis - antigen detection, identification, and specificity;

9. Immunotherapy and immune prophylaxis - development of potential vaccine materials, antiserum therapy;

10. Chemotherapy - development of antifungal agents, pharmacology of antifungal drugs.

III. MECHANISM OF SUPPORT

In fiscal year 1984, the NIAID plans to fund at least two new or competing renewal MRU applications. Each grant will have a duration of not more than five years. Funding beyond the first year of the grant will be contingent upon satisfactory progress during the preceding year and availability of funds.

The receipt date for applications will be October 15, 1983. They will undergo initial review in February-March 1984, and subsequent review by the National Advisory Allergy and Infectious Diseases Council in May 1984. September 1, 1984 will be the earliest starting date for successful applicants.

Grant funds may be utilized to support the research activities of scientific and professional personnel, consultation services, equipment, supplies, travel, and publication costs. Support for research-related costs of patient involvement and medical care may be authorized. Since the program cannot provide funds for new construction, adequate physical facilities must be available for the primary needs of the unit.

IV. LETTER OF INTENT

Prospective applicants are encouraged to submit to the address below, a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institutions. The Institute requests such letters for the purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding. It will not enter into the review of any application subsequently submitted, and is not a necessary requirement for application.

Inquiries should be directed to:

Darrel D. Gwinn, Ph.D.
Mycology Program Officer
Microbiology and Infectious Diseases Program
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 738
Bethesda, Maryland 20205

Telephone: (301) 496-7728

V. REVIEW PROCEDURES AND CRITERIA

These are outlined in the NIAID Information Brochure on Program Projects (see "METHOD OF APPLYING" below).

VI. CONSEQUENCES OF LACK OF RESPONSIVENESS TO THE RFA OR LATE SUBMISSION

Formal applications that are not responsive to the RFA or are not received by October 14, 1983, will not be accepted for review and will be returned to the applicant.

VII. METHOD OF APPLYING

Before preparing an application, the prospective applicant should request a copy of the NIAID Information Brochure on Program Projects from:

Susan Spring, Ph.D.
Executive Secretary
Microbiology and Infectious Diseases
Advisory Committee
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 706
Bethesda, Maryland 20205

Telephone: (301) 496-7465

The Information Brochure contains special instructions for preparing program project grant applications, review procedures and criteria, and other important information.

Use the standard research grant application form PHS 398 (Rev. 5/82). In addition to following accompanying format instructions for the development of a Center application, include expanded material listed above under the eight points for the "letter of intent." For purposes of identification and processing, the words "Mycology Research Unit" should be typed in item 2 on the face page of the application and a brief covering letter should be attached indicating submission is in response to this NIAID announcement.

Application kits may be obtained from the institution's application control office. If not available there, they may be obtained from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 448
Bethesda, Maryland 20205

Forward the complete application to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Please forward a copy (not the original) of the cover letter and the application face page to:

Darrel D. Gwinn, Ph.D.
Mycology Program Officer
Microbiology and Infectious Diseases Program
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 738
Bethesda, Maryland 20205

Telephone: (301) 496-7728

ANNOUNCEMENT

IRISH MEDICAL RESEARCH COUNCIL FELLOWSHIPS

FOGARTY INTERNATIONAL CENTER

The Medical Research Council of Ireland (MRCI) provides a limited number of postdoctoral research fellowships to U.S. health scientists to conduct research in Ireland. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical and behavioral sciences. The types of activity that are supported by this program include collaboration in basic or clinical research, and the familiarization with or utilization of special techniques and equipment not otherwise available to the applicant. The program does not provide support for activities that have as their principal purpose brief observational visits, attendance at scientific meetings, or independent study.

The program is administered for the MRCI through the Fogarty International Center (FIC), National Institutes of Health (NIH).

ELIGIBILITY

Applicants for the program must meet the following requirements:

- U.S. citizenship or permanent U.S. residency,
- A doctorate in clinical, behavioral or biomedical science,
- Ten years or less of postdoctoral experience,
- Professional experience in the health sciences for at least two of the last four years.

SUPPORT

The MRCI will provide the following support:

1. Stipend: Stipends are between IR£10,000 and IR£15,000 per annum. The appropriate level is determined by the age and experience of the applicant at the time of award. Research experience such as teaching, internship, or residency training may be considered relevant experience.

2. Travel: Roundtrip tourist class air fare expenses are provided for fellows from point of origin in the United States to the Irish training institution. Fellows must purchase their flight tickets through the Aer Lingus office in New York or Boston. No reimbursement will be made for any other expenses en route, nor for costs of transporting personal or household effects.

DURATION OF PARTICIPATION

Fellowships are awarded for a one year period, but exceptions may be considered if recommended by the training institution and approved by the MRCI. The starting date of the fellowship is set by mutual agreement of the applicant and the institution, provided it is within the twelve-month period immediately following the date of the award.

APPLICATION AND SELECTION

Information and applications are provided by the Fogarty International Center. In addition to biodata and reference reports, the applicant will be required to include a clear and explicit description of the proposed activity to be carried out in Ireland and the benefit expected from the experience. The sponsor's portion of the application should reflect that he or she is pepared to guide and administer the proposed research project, and can provide the necessary facilities. It is the applicant's responsibility to arrange for his or her research training with the sponsor either through direct correspondence with a scientist in Ireland or through correspondence in the applicant's behalf by a senior scientist in the United States with an Irish colleague.

Deadline for receipt of applications at the Fogarty International Center is October 1. Applications are reviewed for scientific merit by the NIH and are transmitted to the Medical Research Council of Ireland for final selection. Shortly after the MRCI meeting which is held in May, candidates will be notified of the results.

INQUIRIES AND APPLICATION KITS

Chief, International Research and Awards Branch
Fogarty International Center
Building 38A - Room 613
National Institutes of Health
Bethesda, Maryland 20205

ANNOUNCEMENT

BIOMEDICAL RESEARCH FELLOWSHIP OPPORTUNITIES ABROAD

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) of the National Institutes of Health (NIH), announces the availability of postdoctoral fellowships to U.S. health scientists who wish to conduct collaborative research abroad. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical, behavioral and health sciences.

Programs Available to U.S. Citizens or Permanent U.S. Residents:

> ALEXANDER VON HUMBOLDT FOUNDATION POSTDOCTORAL RESEARCH FELLOWSHIPS
> (Supported by the Federal Republic of Germany)
>
> FRENCH NATIONAL INSTITUTE OF HEALTH AND MEDICAL RESEARCH POSTDOCTORAL FELLOWSHIPS
> (Supported by the Government of France)
>
> IRISH MEDICAL RESEARCH COUNCIL POSTDOCTORAL FELLOWSHIP
> (Supported by the Government of Ireland)
>
> NIH-FRENCH NATIONAL CENTER FOR SCIENTIFIC RESEARCH EXCHANGE PROGRAM
> (Jointly Supported by the Governments of France and the United States)
>
> SWEDISH MEDICAL RESEARCH COUNCIL FELLOWSHIPS
> (Supported by the Government of Sweden)
>
> SWISS NATIONAL SCIENCE FOUNDATION POSTDOCTORAL FELLOWSHIPS
> (Supported by the Government of Switzerland)

The eligibility requirements of each program vary and this information is provided in each program's brochure which is available upon request. However, at a minimum, each candidate must have an earned doctoral degree in one of the behavioral, biomedical or health sciences and some postdoctoral experience.

The receipt date for all applications except those to the Alexander von Humboldt Foundation is October 1, 1983. Applications for the Alexander von Humboldt Foundation Postdoctoral Research Fellowships are available and are accepted throughout the year. For those fellowship programs with an October 1 receipt date, application kits will be available from April 1, 1983 to September 15, 1983. The organization that provides financial support for each of the programs selects candidates for participation. While the maximum period of support for all programs is one year, the minimum period of support varies with each program.

All correspondence should refer clearly to the specific program of interest. For further information, please send a self-addressed label with your request to:

International Research and Awards Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

*U.S. GOVERNMENT PRINTING OFFICE : 19[illegible]-0-381-144/204

NIH Guide
for Grants and Contracts

Vol. 12, No. 7, July 15, 1983

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AND HUMAN SERVICES

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

TAXABILITY OF NRSA STIPENDS

**All Holders of National Research Service Awards (NRSA),
NRSA Institutional Training Grant Program Directors,
Directors of Sponsored Programs and Business Officers**

Since the enactment of the NRSA Act of 1974, there has been some ambiguity related to the interpretation of awards made under the Act as scholarship or fellowship grants under section 117 of the Internal Revenue Code that has required repeated legislative action to resolve.

The Director, NIH, recently requested an IRS opinion as to whether NRSAs made under section 472 of the Public Health Service Act (42 U.S.C. 289 1-1), as amended by section 924 of the Omnibus Reconciliation Act of 1981 (Pub. L. 97-35), are entitled to treatment as scholarships or fellowship grants within the meaning of section 117 of the Internal Revenue Code in light of statutory amendments made to section 472 in 1981 and certain facts concerning the program as it has developed over the past several years.

In his response to Dr. Wyngaarden dated June 24, 1983, Gerald G. Portney, Associate Chief Counsel (Technical), Office of Chief Counsel, IRS, Department of the Treasury stated

> "....it is our opinion that National Research Service Awards received by individuals pursuant to the provisions of the National Research Service Awards Act of 1974, as amended, are excludable from the recipients' gross incomes as scholarships or fellowship grants under section 117 of the Code."

Section 117 is that part of the internal revenue code which applies to the treatment of all scholarships and fellowships. In general, it provides that, subject to certain limitations, degree candidates may exclude the full amount of their scholarships or fellowships from their gross income for purposes of taxation and non-degree candidates may exclude up to $300 per month of such awards for up to 36 months.

The interpretation and implementation of the tax laws are the domain of the Internal Revenue Service and the courts. The purpose of this notice is to inform interested parties that there has been a new statement of opinion concerning the law. NIH takes no position on what this change may mean for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the new law to their situations and for information on the proper steps to be taken regarding their tax obligations or claims for current and past tax years.

NOTICE

INSTITUTIONAL TRAINING GRANTS: TRAINING RELATED EXPENSES

National Research Service Award (NRSA) Institutional Training Grant Directors,
Directors of Sponsored Programs and Business Officers

The current level of funds available for training related expenses (formerly called institutional allowances) is such that it is no longer practical to require itemization of the costs for which these funds provide the necessary support. Itemization, therefore, of training related expenses ("above the line") will not be required for awards to be made from FY 1984 funds on NRSA institutional training grants.

Competing and noncompeting applications and awards for FY 1984 NRSA T32 and T35 institutional training grants subject to the ceiling of $1,500 per predoctoral and $2,500 per postdoctoral trainee should no longer itemize the categories from which the expenditures will be made. Training related expenses should be identified as a single figure under SUBTOTAL (Section A) of both PHS 6025-1 and PHS 6025-2. No explanation of this figure is required.

All expenditures charged to NRSAs must continue to be made in accordance with PHS grants policy; however, rebudgeting of funds awarded in lump sum for training related expenses and which have previously required awarding unit prior approval are entirely delegated to the Institutional Prior Approval System. Prior approval of the awarding unit still obtains for the transfer of amounts previously awarded for trainee costs (stipends, tuition and fees) to other categories of expense.

All progress reports should specify the way in which essential program enhancement was achieved through the availability of training related expenses.

NOTICE

CHANGE IN RECEIPT DATE

REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

NIH-NCI-DRCCA-OSP-83-2

ADMINISTRATIVE COORDINATING CENTER FOR THE ORGAN SYSTEMS PROGRAM

NATIONAL CANCER INSTITUTE

This RFA was originally published in the March 25, 1983 issue of the **NIH Guide for Grants and Contracts, Vol. 12, No. 3**. This announcement extends the application receipt date to August 15, 1983.

The Division of Resources, Centers and Community Activities (DRCCA) of the National Cancer Institute (NCI) invites cooperative agreement applications from institutions capable and interested in establishing a Coordinating Center for the Organ Systems Program. This Request for Applications (RFA) will be utilized to initiate a program in an area of special importance to the National Cancer Program. All applications received in response to this RFA will be reviewed by the same National Institutes of Health (NIH) initial review group. An applicant if funded under this RFA will be supported through the cooperative agreement award in accordance with the policies of the Public Health Service (PHS) and NIH.

The awardee will have the primary responsibility for the planning and direction of the proposed Organ Systems Coordinating Center (OSCC). This will involve active participation and interaction with the NCI Organ Systems Program staff. NCI staff will work closely with the Coordinating Center staff on both administrative and scientific program activities as well as in the annual evaluation of program priorities. NCI staff will periodically review progress to ensure that the Center conforms to the purposes and objectives of the program, as well as conditions of the award. The Board of Scientific Counselors of the DRCCA and the National Cancer Advisory Board will oversee these activities.

Inquiries regarding this announcement or requests for copies of the original RFA should be directed to:

Andrew Chiarodo, Ph.D.
Chief, Organ Systems Program Branch
Division of Resources, Centers and
  Community Activities
National Cancer Institute
Blair Building - Room 3A05
8300 Colesville Road
Silver Spring, Maryland 20910

Telephone: (301) 427-8818

ANNOUNCEMENT

NOTICE OF AVAILABILITY: RFA

COOPERATIVE AGREEMENTS FOR NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS

DIVISION OF CANCER TREATMENT (DCT)

NATIONAL CANCER INSTITUTE (NCI)

Application Receipt Date: October 17, 1983

A prior announcement, **"Participants Sought for National Cooperative Drug Discovery Groups"** **(NIH Guide for Grants and Contracts, Vol. 11, No. 13, December 3, 1982)** invited leading scientists from academia, research institutions, and industry to submit expressions of interest in participating in National Cooperative Drug Discovery Groups (NCDDG) and indicated DCT plans to issue a Request for Application (RFA) outlining the specifics of the program.

The RFA is available from:

Dr. John M. Venditti
Chief, Drug Evaluation Branch
Blair Building - Room 428
National Cancer Institute
Bethesda, Maryland 20205

The closing date for applications is October 17, 1983.

Applicants are not restricted to those who responded to the December 1982 Announcement.

SUMMARY

Exciting leads in molecular biology, medicinal and organic chemistry, biochemistry, and pharmacology present unprecedented opportunities for design and pre-clinical evaluation of powerful new entities and strategies for the treatment of cancer. Exploitation of these leads and their extrapolation to new treatments can be accomplished by mobilizing the most creative scientists in a number of scientific disciplines regardless of their organizational affiliation. The NCDDG program will assist these scientists to interact, with NCI support, as a unit. It is envisioned that each NCDDG will be multi-disciplinary and multi-institutional; and will consist of a Group Director and a number of Program Leaders. The Group Director will be responsible for the application and for performance of the Group and will be accountable for funds awarded. Thus, each NCDDG will have capacity to generate new inventions, to translate rapidly their concepts into new treatments, to conduct adequate pre-clinical biological evaluations, to carry out biochemical and pharmacological studies at the pre-clinical level, and to identify new treatment entities worthy of development to clinical trial.

Awards will be made as Cooperative Agreements. These are assistance relationships involving substantial involvement of NCI staff during performance of the project. The nature of NCI staff participation is included in the RFA. However, the applying Group must define its objectives in accord with its own interests and perceptions of novel approaches to the discovery of more effective cancer treatment. The role of NCI staff will be to provide assistance, advice, and guidance via information input at Group meetings. Final decision-making authority during performance will rest with the Group Director.

NCI hopes to make multiple awards for project periods of five years and has set aside $2,000,000 for the initial year's awards.

ANNOUNCEMENT

NOTICE OF AVAILABILITY: RFA

COOPERATIVE AGREEMENTS FOR A PHASE III TRIAL OF A LOW FAT DIET IN WOMEN WITH STAGE II BREAST CANCER

NIH-NCI-DRCCA-DCB 83-5

NATIONAL CANCER INSTITUTE

Letter of Intent Receipt Date: September 15, 1983
Application Receipt Date: October 17, 1983

The Division of Resources, Centers, and Community Activities (DRCCA), and the Division of Cancer Treatment (DCT), National Cancer Institute (NCI), invite applications for cooperative agreements to support participation in a multi-institution randomized clinical trial of a low fat diet (20% of calories) aimed at prolonging the disease-free survival and overall survival in surgically-staged breast cancer patients who have involvement of the axillary lymph nodes. The investigators will identify, enroll and follow participants in this trial using a protocol developed jointly by the investigators and NCI staff.

Applications are solicited to fund participants in three categories: 1) clinical units, 2) nutritional coordinating unit(s), and 3) a statistical coordinating unit. Applicants may apply for more than one category (clinical, nutrition, statistical), but the applications should be cast as separate documents for review. The requirements for each of these units are outlined in the complete Request for Application (RFA).

The trial, a single protocol, will be initiated in three stages. The first stage will involve a meeting between the investigators and NCI staff for the purpose of writing the protocol for this study. The second stage will be a feasibility study, during which the protocol will be implemented at three institutions (selected on the basis of priority score and accrual potential) with particular emphasis on documenting protocol adherence in the study and control groups. In stage three the protocol will be implemented in all remaining clinical units.

Copies of the complete RFA and additional information may be obtained from:

Ritva Butrum, Ph.D.
Diet, Nutrition and Cancer Branch
National Cancer Institute
Blair Building -Room 619
Bethesda, Maryland 20205

Telephone: (301) 427-8753

To ensure their review, applications must be received by October 17, 1983.

ANNOUNCEMENT

PHYSICIAN SCIENTIST AWARD

NATIONAL INSTITUTE ON AGING*
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES*
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF DENTAL RESEARCH
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES*
NATIONAL EYE INSTITUTE
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Initial Application Receipt Date: October 17, 1983
Subsequent Receipt Dates: February 1, June 1, October 1

The National Institutes of Health (NIH) announces the availability of the Physician Scientist Award to be supported by those institutes listed. The award is intended to encourage newly trained clinicians to develop independent research skills and experience in a fundamental science.

These awards provide the opportunity for clinically trained professionals with a commitment to research to develop into independent biomedical investigators. Two types of awards are available: the program award and the individual award.

The awards will enable physicians with clinical training to undertake up to five years of special study in basic science with a supervised research experience. The first phase (two to three years) of the program will include both didactic study and laboratory experience conducted under the close sponsorship of an individual with extensive research experience in fundamental sciences. The second phase (up to three years) under the continuing guidance of this primary sponsor, will be to apply laboratory-based research in either a basic science or clinical department. This award requires a commitment from a sponsor with extensive fundamental research experience within a basic science department such as (but not limited to) biochemistry, molecular biology, genetics, or immunology, and a research program plan using a fundamental or clinical science approach to disease related problems.

In summary, the Physician Scientist Award is designed to encourage the individual with clinical training to develop research skills in a fundamental science. To help support the transition from clinical training status to that of a productive investigator able to compete successfully for NIH research support, the Physician Scientist Award will provide the opportunity for clinicians to develop into independent investigators, to obtain research experience under the sponsorship of a basic research scientist and to initiate a research program.

* These three institutes also offer the program award.

I. ELIGIBILITY

A. These awards are designed to provide an intensive, supervised research experience or clinicians. Thus, candidates are restricted to those holding health professional degrees in the clinical sciences (M.D., D.D.S., D.V.M., D.O. or equivalent). Physicians holding the PhD are ineligible. Candidates ordinarily will have completed at least one post-graduate year of clinical training by the time the award is made.

B. Candidates should demonstrate competence in clinical activities, and should show research potential. Candidates must provide evidence of a serious intent for research and academic careers.

C. Candidates for an award must be citizens or non-citizen nationals of the United States or its possessions and territories or must have been lawfully admitted to the United States for permanent residence at the time of application.

D. Applicants for a Physician Scientist Award may not submit a concurrent application for an NIH Research Career Development Award, Academic Award, a Clinical Investigator Award or a Special Emphasis Research Career Award. Physician scientist awardees may subsequently apply for a New Investigator Research Award or a research project grant.

E. Ordinarily a candidate with previous independent NIH research support or its equivalent will not qualify.

II. MECHANISMS OF AWARD

This award may be supported through two mechanisms: the individual award and the program award.

A. Individual Awards

1. The Environment

Applications will be accepted from a domestic university, medical school, or comparable institution with strong, well-established research and training programs, adequate numbers of highly trained faculty in clinical and basic science departments, and commitment and capability to provide guidance to clinically trained individuals in the development of independent research careers. The environment desired is one which will stimulate and increase the interaction between basic scientists and clinical investigators.

Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation, and potential for a research career. Evidence of the commitment of the institution to the candidate's research and development must be provided.

2. The Program

The individual's program should be designed in two phases. The candidate must provide a description of the research development plan. It should start with a creative and detailed basic science learning experience in Phase I and progress to culminate in intensive research activity in Phase II under the general guidance of a qualified sponsor. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of Phase I. This report is to contain specific information concerning progress and accomplishments and, in particular, an appropriately detailed Phase II research plan and protocol for administrative review and approval.

3. Sponsor

Each candidate must identify a primary sponsor who is recognized as an accomplished investigator in the basic science research area proposed and who will provide the guidance for the awardee's development and research plan. The primary sponsor must be committed to continue this involvement through the individual's total period of development under the award. In some cases candidates may elect to have a secondary clinical sponsor for the research intensive years.

4. Duration and Effort

This five year non-renewable award is based on up to five consecutive full-time 12 month appointments. All funds must be used on behalf of the original candidate. Support is divided into two distinct phases that relate to the individual's progress in becoming an independent investigator. It is required that a minimum of 75 percent effort be devoted to the research program. The balance of effort can be devoted to other clinical and teaching pursuits only if they are consonant with the program goals, i.e., the awardee's development into an independent biomedical research investigator.

It is desirable for individuals to complete both phases without interruption. It may be permissible, however, to interrupt the award and delay the start of Phase II in order to engage in further clinical training. In the event such a contingency arises, the awardee and the sponsor must justify the interruption to the awarding institute to assure that funds will be available to resume the award so that the candidate may complete the program.

5. Allowable Costs

a. Salary -- Individual compensation based on the institution's salary scale for residents at an equivalent experience level but funding from this award for salary not to exceed $30,000 per year per individual plus commensurate fringe benefits for essentially full-time (75-100 percent) effort to the endeavor.*

b. Sponsor's Support — A sum of up to 10 percent of the primary sponsor's salary and commensurate fringe benefits during Phase I.

c. Research and Development Support — $10,000 per year increasing to $20,000 per year in Phase II for research project requirements and related support, e.g., technical personnel costs, supplies, equipment, candidate travel, medical insurance premiums and tuition for necessary courses.

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* NIH policy encourages supplementation from non-government sources, e.g., voluntary or professional organizations.

d. Indirect Costs -- reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees and expenditures for equipment.

6. Concurrent Awards

Individuals entering Phase II are encouraged to apply for separate research support. Such support may be applied for and held with no reduction in the $20,000 provided as research support. However, salary support from PHS sources above the $30,000 provided by this award is not allowable.

B. Program Award

1. The Environment

Applications will be accepted from an association of departments and divisions and/or clinical departments representing a range of research interests. The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established research and training programs with adequate numbers of highly trained faculty in clinical and basic sciences and with the interest and capability to provide guidance to clinically trained individuals in the development of research independence. The environment sought is one which will stimulate and increase the interaction between basic scientists and clinical investigators.

2. Program Director

The proposed Program Director should possess the scientific expertise, leadership and administrative capabilities required to coordinate and supervise an interdisciplinary research and development program of this scope. The Director should also be experienced in the design and management of programs for developing investigators, and should be able to demonstrate a superior record in the preparation of clinical investigators for independent research. In addition, a committee with representatives from the appropriate basic and clinical science departments shall be established to advise the Program Director.

3. Sponsor

Each awardee appointed on the grant must have a primary sponsor who is recognized as an accomplished investigator, actively involved in basic science research who will provide the guidance for the awardee's development and research plan. The primary sponsor must be committed to continue this involvement through the individual's total period of development under the award. In some cases awardees may elect to have a secondary clinical sponsor for the research intensive years.

4. Program

The Program award provides five years of renewable support. The award is intended to provide up to five years support of consecutive full-time 12 month appointments to each individual candidate appointed. This support is divided into two distinct phases that relate to the individual's progress in becoming an independent investigator. The support starts with Phase I which is to be a creative and detailed basic science learning experience and culminates in Phase II which requires intensive research under the general guidance of a qualified sponsor.

It is desirable for individuals to complete both phases without interruption. It is permissible, however, to delay the start of Phase II in order to engage in clinical training. In the event such a delay occurs, it is expected that the program director will plan to provide the necessary resources for the awardee to reenter and complete the program. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of Phase I. This report is to contain specific information concerning progress and accomplishments and, in particular an appropriately detailed Phase II research plan and protocol for administrative review and approval.

5. Duration, Effort and Allowable Costs: Support may be requested for up to two postdoctoral candidates entering Phase I per budget period.

   a. Salary -- Compensation for candidate based on the institution's salary scale for residents at an equivalent experience level but funding from this award is not to exceed $30,000 per year per individual plus commensurate fringe benefits for essentially full-time (75-100 percent) effort to the endeavor.*

   b. Sponsor's Support -- A sum of up to 10 percent of the primary sponsor's salary and commensurate fringe benefits during Phase I.

   c. Research and Development Support -- $10,000 per year increasing to $20,000 per year in Phase II per candidate for research project requirements and related support, e.g., technical personnel costs, supplies, equipment, candidate travel, medical insurance premiums and tuition for necessary courses.

   d. Indirect Costs -- reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees and expenditures for equipment.

6. Budgeting for Future Years

Critical to the success of this program award is the ability of the Program Director to make detailed mid-course assessments of each candidate's developing research skill and of the proper time for transition from one phase to another. It is expected that applicant institutions will initiate their activities under this award in a staged manner. That is, the first requested year of support would include funds for candidates in Phase I only. The second year would request funds for new candidates in Phase I as well as for continued funding of the first year's supported individuals. In this way, the requested level of support would increase steadily from the 01 through the 05 budget period as new candidates were appointed.

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* NIH policy encourages supplementation from non-government sources, e.g., voluntary or professional organizations.

7. Concurrent Awards

Individuals entering Phase II are encouraged to apply for separate research support. Such support may be applied for and held with no reduction in the $20,000 provided as research support. However, salary support from PHS sources above the $30,000 provided by this award is not allowable.

III. EVALUATION

Awardees must agree to inform the National Institutes of Health annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

IV. MECHANISM OF SUPPORT

The mechanism of support for this activity will be the research grant, awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended, 42 USC 241). The regulations (Code of Federal Regulations, Title 42 Part 52, and Title 45 Part 74) and policies which govern the research grant programs of the National Institutes of Health (NIH), will prevail.

The award of grants pursuant to this announcement is contingent upon availability of appropriated funds.

V. METHOD AND CRITERIA OF REVIEW

Applications will be received by the NIH Division of Research Grants (DRG), and, governed by normal programmatic considerations as specified in the NIH Referral Guidelines, will be assigned to the appropriate institute for possible funding.

Applications in response to the Announcement will be reviewed in nationwide competition, and in accordance with the usual NIH peer review procedures. They will first be reviewed for scientific and technical merit by an institute review group composed mostly of non-Federal scientific consultants (initial review group). Following this review, the applications will be evaluated by the appropriate Institute Advisory Council (IAC).

VI. APPLICATION PROCEDURES

Initial Receipt Date: October 17, 1983, will be the first receipt date for applications to be considered by the February 1984 National Advisory Councils for Awards to be made in the spring of 1984. Normally, an original and six copies of an application are mailed to the Division of Research Grants (DRG). For the initial receipt date, October 17, 1983, the original and five copies should be mailed to DRG and one copy to the institute contact person. The outside of the envelope should be identified as **PHYSICIAN SCIENTIST AWARD.**

Future Receipt Dates: Deadlines for receipt of applications by the Division of Research Grants, NIH, are as follows:

Applications Received by	Presented to Council in	Earliest Requested Beginning Date
February 1	September/October	December 1
June 1	January	April 1
October 1	May	July 1

For further details and in order to obtain an application kit contact the person listed below in the institute offering awards in your area of research interest.

NATIONAL INSTITUTE OF AGING

Edward L. Schneider, M.D.,
Associate Director
Biomedical Research and Clinical Medicine
National Institute on Aging
National Institutes of Health
Building 31 - Room 5C11
Bethesda, Maryland 20205

Telephone: (301) 496-4996

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

John W. Diggs, Ph.D.,
Director of Extramural Activity Programs
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 703
Bethesda, Maryland 20205

Telephone: (301) 496 7291

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISORDERS

Alan Moshel, M.D.,
National Institute of Arthritis, Diabetes. and
Digestive and Kidney Diseases
National Institutes of Health
Westwood Building - Room 405
Bethesda, Maryland 20205

Telephone: (301) 496-7326

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Duane Alexander, M.D., (301) 496-1848
Deputy Director
National Institute of Child Health
and Human Development
National Institutes of Health
Building 31 - Room 2A04
Bethesda, Maryland 20205

Telephone: (301) 496-1848

NATIONAL INSTITUTE OF DENTAL RESEARCH

Anthony Rizzo, D.M.D., (301) 496-7748
Deputy Associate Director for
Extramural Programs
National Institutes of Dental Research
National Institutes of Health
Westwood Building - Room 507
Bethesda, Maryland 20205

Telephone: (301) 496-7748

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Christopher Schonwalder, Ph.D.,
Scientific Director for Extramural
Training Programs
National Institute of Environmental
Health Sciences
National Institutes of Health
P.O. Box 12233
Research Triangle Park, North Carolina 27709

Telephone: (919) 541-7634

NATIONAL EYE INSTITUTE

Ronald Geller, Ph.D., (301) 496-4903
Associate Director for Extramural and
Collaborative Programs
National Eye Institute
National Institutes of Health
Building 31 - Room 6A03
Bethesda, Maryland 20205

Telephone: (301) 496-4903

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Jerome G. Green, M.D., (301) 496-7416
Director, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building - Room 7A17
Bethesda, Maryland 20205

Telephone: (301) 496-7416

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

RFA-NIH-NHLBI-DBDR-83G-K

ASSAY METHODS TO DETECT THE CARRIER STATE OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application receipt date: October 17, 1983

I. PURPOSE

The Division of Blood Diseases and Resources (DBDR) invites grant applications for the development of tests to identify the carrier state of acquired immunodeficiency syndrome (AIDS) and to evaluate the sensitivity and specificity of these tests. The major purpose of this special grant program is to determine whether there are markers for AIDS that can be used to rapidly, simply, and specifically identify individuals who are asymptomatic carriers of AIDS.

II. DISCIPLINES AND EXPERTISE

Among the disciplines and expertise that may be appropriate for this research program are immunology, virology, microbiology, hematology, pathology, blood banking sciences, oncology, hepatology (gastroenterology), and infectious diseases.

III. BACKGROUND

A. Administrative Background: The Blood Resources Branch (BRB) of the DBDR designs and administers programs related to the safety of blood therapy. The Branch specifically supports research on the development of methods to detect transfusion-transmitted diseases. The AIDS epidemic has become a major public health problem. The etiology and mode of transmission of the disease are unknown. However, there is increasing concern that a possible mode of transmission is through blood transfusion. The National Heart, Lung, and Blood Institute (NHLBI) has been designated as the lead Institute at the National Institutes of Health (NIH) for the development and evaluation of screening procedures for identifying donors who are at increased risk for transmitting AIDS.

This program is described in the Catalog of Federal Domestic Assistance No. 13.839, Blood Diseases and Resources. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

B. Scientific Background: Since the summer of 1981, more than 1,500 cases of a disorder characterized by a defect in the cell-mediated immune system have been reported to the Centers for Disease Control (CDC) from 34 states, the District of Columbia, and 15 countries; this disease is now known as acquired immunodeficiency syndrome (AIDS). The chief clinical manifestations are Kaposi's sarcoma and opportunistic infections. Reported cases have increased from an average of one case per day in 1981, to three to four daily in late 1982 and early 1983. Over 550 persons have died, with the case-fatality rate exceeding 60 percent for cases diagnosed more than 1 year previously.

Previously, Kaposi's sarcoma was a rare disorder usually manifested in elderly males while opportunistic infections, such as Pneumocystis carinii pneumonia, generally occurred in immunocompromised patients. The cases of AIDS encompass different risk groups--young male homosexuals, male and female heterosexuals who abuse intravenous drugs, and recent male and female Haitian immigrants. Patients also include heterosexual hemophiliacs with no history of intravenous drug abuse and no previous underlying immunosuppressive disorder. AIDS has also been reported in children of mothers whose sexual partners have developed the syndrome as well as in some transfusion recipients who are in none of the risk categories mentioned above.

The etiology of AIDS is unknown. It has been proposed that viral infection or antigenic overload could lead to this immune deficiency. Either mechanism would affect blood product recipients as well as most of the risk groups identified above. This solicitation, however, is based on the assumption that a specific infectious agent(s) is involved, that the disease is transmissible parenterally, and that methods can be found to identify asymptomatic individuals who carry the putative agent(s). The distribution and mode of spread of AIDS are believed to be similar to those of hepatitis B virus, which occurs frequently in AIDS patients as well as in groups at high risk for AIDS.

A number of tests have been suggested to identify asymptomatic individuals with AIDS; however, none has the sensitivity or specificity necessary for identifying asymptomatic AIDS victims or excluding their blood from the donor pool. Furthermore, the more specific tests are very complicated and unsuitable for routine use. Direct and indirect tests currently in use include the identification of various serum proteins related to the immune system, measurement of T-cell subset ratios, lymphocyte function evaluations, and measurement of hepatitis B core antigen. Several indirect tests for identifying carriers of AIDS have recently been suggested, including procedures for quantitating alpha-1-thymosin, beta-4-thymosin, beta-2-microglobulin, and acid-labile-alpha interferon. Recent reports suggest that antibody to human T-cell lymphoma-leukemia virus (HTLV) might be of value as a marker for AIDS. Alpha-1-thymosin, beta-4-thymosin, and beta-2-microglobulin have been studied in AIDS patients, New York City homosexuals, and apparently normal blood donors. Results from these assays have been ambiguous; however, in two homosexuals, beta-2-microglobulin levels increased progressively over the 3-year period before the onset of AIDS. Acid-labile-alpha interferon is also a possible marker. One study showed that over 60 percent of homosexual males with AIDS had higher serum concentrations of acid-labile-alpha interferon; three hemophiliacs with AIDS had higher concentrations of acid-labile-alpha interferon while interferon levels in 48 normal hemophiliacs were normal; and in two of the three hemophiliacs with AIDS, circulating acid-labile-alpha interferon rose to detectable levels 3 to 10 months before the appearance of any clinical symptoms. A recent study detected antibody to HTLV in 25 percent of homosexuals with AIDS and in only 1 percent of individuals in the control group.

While the significance of these preliminary observations is not yet known, such markers might be useful as an interim screening procedure in identifying symptomatic carriers of AIDS. Further evaluation of the sensitivity and specificity of these and other assays, as well as the development of new, rapid, simple, specific, sensitive direct tests, is urgently needed.

IV. OBJECTIVES AND SCOPE

Although the etiology of AIDS is unknown, the theory that a specific infectious agent is involved has gained support within the scientific community. Currently, there are no laboratory methods that specifically identify individuals who are asymptomatic carriers of AIDS. A test to identify such individuals would be extremely helpful in excluding them from the blood donor pool, particularly if it were applicable at the time of blood donation.

The purpose of this special grant program is to develop and validate methods that can rapidly, simply, and specifically identify individuals who have AIDS, either diagnosed or asymptomatic.

There is no validated animal model for AIDS. Therefore, studies supported by this RFA will deal primarily, if not exclusively, with human material. Precautionary measures for clinical and laboratory staff have been published and should be followed (CDC Morbidity and Mortality Weekly Report, Vol. 31, No. 43, November 5, 1982); these are similar to those used with patients and material suspected to have hepatitis B virus.

The research supported by this program will have as its objective the identification of specific markers for AIDS. Studies that focus on isolation of virus(es), development of animal models, or clinical diagnostic criteria for AIDS will not be responsive.

Investigators are encouraged to initiate new and innovative approaches that may lead to the development and validation of new tests that are more specific, more discriminating and more cost-effective than existing procedures. The knowledge gained in such a basic science approach is also likely to enhance our understanding of the pathophysiology of the disease.

V. MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional, individual, investigator-initiated research project grant. The NHLBI plans to designate for fiscal year 1984 the sum of $1,500,000 for the total (direct and indirect) costs of this program. It is anticipated that 8 to 10 grants will be awarded under this program. The specific amount of grant support will, however, depend on the merit and scope of the applications received and the availability of funds. Since a variety of approaches would represent valid responses to this announcement, it is anticipated that there will be a range of costs among individual grants awarded.

Upon initiation of the program, the DBDR will sponsor periodic meetings to encourage exchange of information among investigators in this program. In the preparation of the budget for the grant application, applicants should request travel funds for a 2-day meeting each year, most likely to be held in Bethesda, Maryland. Applicants should also include a statement in their application indicating their willingness to participate in such meetings.

Applicants will plan and execute their own research programs. They are requested to furnish estimates of the time required to achieve the objectives of the proposed research project. At the end of the initial award period, renewal applications may be submitted for further competitive review through the regular grant program of the NIH. It is anticipated that support will begin on April 1, 1984.

VI. REVIEW PROCEDURES AND CRITERIA

A. Review Method: All applications submitted in response to this RFA will be reviewed for scientific and technical merit by an initial review group, which will be convened by the Division of Extramural Affairs, NHLBI, solely to review these applications. Upon receipt, applications will be reviewed for their responsiveness to the objectives of this RFA. If an application is judged unresponsive at this stage, the applicant will be contacted and given an opportunity to withdraw the application or to have it considered for the regular research grant program of the NIH.

If a proposal submitted in response to this RFA is substantially similar to a research grant application already submitted to the NIH for review, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed.

B. Review Criteria: The factors to be considered in the evaluation of scientific merit of each application will be similar to those used in the review of traditional research-project grant applications, including the novelty, originality, and feasibility of the approach; the training, experience, and research competence of the investigator(s); the adequacy of the experimental design; the suitability of the facilities; and the appropriateness of the requested budget to the work proposed. An additional review criterion will be an assessment of the importance of the proposed research to the objectives of this RFA.

VII. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to submit a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institution(s). The Institute requests such letters for the purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding, and it will not be considered in the review of any application later submitted, nor is it a requirement for application. The letter of intent, which should be received no later than August 15, 1983, should be sent to:

Dr. Charles L. Turbyfill
Westwood Building - Room 553
Review Branch, DEA, NHLBI
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7351

B. Format for Applications

Submit applications on form PHS 398, the application form for the traditional research-project grant. This form is available in an applicant institution's office of sponsored research or business office. Use the conventional format for research-project grant applications and ensure that the points identified in the Section on "Review Procedures and Criteria" are fulfilled.

To identify the application as a response to this RFA, check "yes" on item 2 of page 1 of the application and enter the title ASSAY METHODS TO DETECT THE CARRIER STATE OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) and the RFA number NIH-NHLBI-DBDR-83G-K.

C. Application Procedure

Send or deliver the completed application and six (6) signed, exact photocopies of it to:

Division of Research Grants
Westwood Building - Room 240
National Institutes of Health
Bethesda, Maryland 20205

Send an additional 20 copies of the application to:

Review Branch, DEA, NHLBI
Westwood Building - Room 5A15
National Institutes of Health
Bethesda, Maryland 20205

Applications must be received by October 17, 1983. If an application is received after this date, the applicant will be contacted and given the option of having the application returned or considered in the next regular application review cycle.

D. Timetable

Letter of intent:	August 15, 1983
Application receipt date:	October 17, 1983
Review by the National Heart, Lung, and Blood Advisory Council:	February 9-10, 1984
Expected award date:	April 1, 1984

E. Inquiries

Inquiries regarding this announcement may be directed to the program administrator:

Dr. Luiz H. Barbosa
Federal Building - Room 5C06
Blood Resources Branch, DBDR,
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-1537

ANNOUNCEMENT

TRANSFUSION MEDICINE ACADEMIC AWARDS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: October 17, 1983

The Division of Blood Diseases and Resources (DBDR), National Heart, Lung, and Blood Institute (NHLBI), announces a second national competition for Transfusion Medicine Academic Awards to: 1) encourage the development of curricula in transfusion medicine, and 2) allow the awardee to broaden his or her experiences in transfusion medicine so that he/she can contribute to the teaching, research, and clinical needs of this discipline. This five-year award supports experienced investigator-faculty members, who are skilled organizers and negotiators, in their efforts to implement a transfusion medicine program. Each school of medicine or osteopathy in the United States or its possessions and territories is eligible for one award (non-renewable) which provides salary, fringe benefits, supporting costs, and indirect costs.

For the purposes of the Transfusion Medicine Academic Award, the term "transfusion medicine" is used to define a multidisciplinary area concerned with the proper use or removal of blood and its components in the treatment or prevention of disease states (other than in renal hemodialysis).

The DBDR initiated the Transfusion Medicine Academic Award Program in January 1983 to encourage a systematic approach to the development of teaching programs in transfusion medicine. Presently, teaching, research, and clinical responsibilities in transfusion medicine are rarely coordinated into a definable program. These components are usually dispersed among basic and clinical science disciplines and among activities of the local transfusion services or blood center facility. In the development of the Transfusion Medicine concept it is important to remember that the teaching of transfusion medicine may not require additional curriculum time. Existing teaching materials (components of other disciplines) may be coordinated into an overall program and organized to focus on emerging and important areas of transfusion medicine. Some schools may find it desirable to assemble the appropriate components into a specific unit. Others may wish to retain the transfusion medicine discipline as part of another major clinical or laboratory department.

This award is intended to:

- encourage the development of effective multidisciplinary curricula in transfusion medicine through the continuum of medical education;

This program is described in the Catalog of Federal Domestic Assistance, No. 13.839, Blood Diseases and Resources. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

- attract and develop faculty, outstanding students, and promising young physicians and scientists who can serve the teaching, research, and clinical aspects of transfusion medicine;
- facilitate interchange of information and educational techniques among research, medical, and blood service communities; and
- allow time for the grantee institution to develop the ability to continue the transfusion medicine program, using local funds, when this award terminates.

Applications must be received by October 17, 1983, for review at the May 1984 meeting of the National Heart, Lung, and Blood Advisory Council. Awards will be made September 1984, depending on the availability of funds.

To receive a copy of the Program Guidelines, please contact:

Fann Harding, Ph.D.
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 5A08
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1817

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

RFA-NIH-NICHD-CPR-DBSB-83-1

ANTECEDENTS AND CONSEQUENCES OF VOLUNTARY CONTRACEPTIVE STERILIZATION

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: December 15, 1983

I. BACKGROUND

The Demographic and Behavioral Sciences Branch ((DBSB), Center for Population Research (CPR), supports research on the antecedents and consequences of fertility and family planning. This RFA invites scientists to submit grant applications for the support of research on an important aspect of fertility and family planning, the antecedents and non-medical consequences of voluntary contraceptive sterilization of women and men.

Contraceptive sterilization is widely used in the United States and throughout the world, and the utilization of the method continues to increase. However, well-designed behavioral-social research leading to definitive results has failed to keep pace with the use of sterilization. Enough is known about the demographic, social, psychological, and economic significance of the operation to emphasize the need for research aimed at increasing knowledge and understanding of its antecedents and consequences.

There have been a considerable number of studies of contraceptive sterilization which have provided some interesting and useful data. However, many of the studies are open to question because of problems of theory, design, methodology, or data analysis. Previous studies have tended to be primarily descriptive. This suggests that more attention could be paid to the interactive effects of antecedents as well as to the improvement of approaches to data analysis. There is need, also, for research which will provide better developed theoretical-conceptual frameworks than some of those which have been used. Among other things, more consideration might be given to the role of sterilization in family planning programs and in fertility regulation by individuals.

This program is supported under Title III, Section 301 and Title IV, Section 441 (Public Law 78-410, as amended; 42USC 241) and described under the Catalog of Federal Domestic Assistance No. 13.864, Population Research. Awards will be administered under PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

It is anticipated that researchers will attempt to develop well-defined and reliable measures of the antecedents and consequences of sterilization. Furthermore, standardized measuring instruments might be utilized where possible. Applicants should be aware that the design of research on sterilization needs to deal with some special problems, particularly with regard to the establishing of control groups and the utilization of sampling techniques. Innovative approaches to such problems would contribute to research efforts in this field.

II. RESEARCH GOALS AND SCOPE

This RFA is meant to encourage investigators to develop necessary and significant research projects which will deal with the limitations of many of the past studies. To accomplish this objective, a thorough analysis of the literature relevant to a proposed project is required. On the basis of this review, the applicant can indicate the reasons for conducting the proposed study, whether it be to fill gaps in knowledge, clarify controversial findings, test hypotheses, and/or improve the research design and methodology relevant to studies of sterilization. The research may be multidisciplinary or may be conducted within a single discipline. Comparative, crosscultural, transnational, or historical approaches may be utilized.

Antecedents - The antecedents of the utilization of contraceptive sterilization may also, together with the operation itself, contribute to the consequences of the sterilization. What are the factors which facilitate or inhibit the choice and use of contraceptive sterilization by individuals and couples, and by family planning clinics? How is the use of sterilization related to the use of other methods of fertility regulation? At what points in the life span are decisions made concerning the use of sterilization, including the decision as to which member of the couple should have the operation? What factors affect decisions concerning the use of contraceptive sterilization? Such factors may include age, sex, marital status, number of children, family size preferences, health, relevant knowledge, education, religion, socioeconomic status, race, ethnic background, and place of origin and residence. There is need to ascertain the contributions of such psychosocial factors as motivations, partner and family relations, attitudes, personality characteristics, psychological and social adjustments, and emotional stability to the decision-making process. Experiences with and attitudes toward prior contraceptive practices, reasons for previous switching of contraceptives, if any, and present desire to change, should be taken into consideration. How do access to services as well as characteristics of service providers and delivery systems affect the decision to be sterilized? What part do various kinds of counseling play in the process?

How do such contextual factors as living situations and events, the media, and societal attitudes affect the decisionmaking?

One goal of the studies of antecedents would be to develop measuring instruments which would indicate the degree of risk of adverse effects as well as the probability that reversal of the operation might be desired some time after the procedure.

Consequences - In conducting research on the consequences of contraceptive sterilization, the interacting effects of the operation and its antecedents on such consequences should be elucidated whenever possible. In general terms, what are the demographic, psychological, sexual, health, social, economic, and other consequences of sterilization at the individual, familial, and societal levels? How and why do such consequences change over time? Are there differences in the effects of the various surgical methods?

What is the effect of contraceptive sterilization, when compared with other methods of fertility regulation, on birth rates, particularly in the United States? For purposes of clarification and hypothesis testing, comparative studies of the United States and other countries could be made.

Quite a number of studies of consequences, especially psychological and sexual ones, have been conducted. However, there is still need for investigations with better defined and measured antecedents and consequences, as well as improved research design and sampling. Many previous studies tend to provide relatively simple statistical indicators of consequences without the use of control groups. Others do not present a conceptual framework which would contribute to both study design and interpretation of results. How does the operation affect such factors as emotional stability, psychological and social adjustment, relevant attitudes and personality characteristics, partner relations, sexual behavior, and familial relationships? How do the various consequences relate to and interact with one another?

Do changes in consequences occur over time and, if so, what are the factors contributing to such changes? Will it be possible to develop techniques to predict adverse changes over time with a view toward finding ways of eliminating them?

How frequently do sterilized individuals seek a reversal of the operation? What contributes to such requests? What are the effects of being unable to obtain a reversal?

III. MECHANISM OF SUPPORT

The support mechanisms for this program will be the individual research project grant and the New Investigator Research Award (NIRA). Although this solicitation is included in the plans for Fiscal Year 1984, the support of grants to be awarded as a result of this RFA is contingent upon the receipt of funds for this purpose. It is anticipated that up to five grants will be awarded, depending on the overall merit of the applications and available funds. It is probable that there will be a range of costs among the grants which are awarded.

Applicants will furnish estimates of the time which will be required to conduct the proposed research. Ordinarily, grants are supported from one to a maximum of five years, but may be renewed according to the conventional processes available through the NIH grant program.

The current policies and requirements that govern the research grant programs of NIH will prevail.

IV. REVIEW PROCEDURES AND CRITERIA

Applications submitted in response to this RFA will be reviewed for scientific merit by an initial review group (IRG) established and administered by the Division of Research Grants (DRG) of the National Institutes of Health (NIH). Applications judged by the DRG and the National Institute of Child Health and Human

Development (NICHD), as nonresponsive to this RFA will be assigned to the most appropriate regular grant program in the Public Health Service (PHS). If such an assignment is not possible, the application will be returned to the applicant. If an application submitted in response to this RFA is the same as one already submitted to the NIH, the applicant will be asked to withdraw the pending application before the new one is accepted.

The factors to be used in evaluating the scientific merit of each application will be similar to those used in judging individual research project grant applications, including originality of the proposed research and feasibility of approach; quality of theoretical-conceptual framework; adequacy of research design; appropriateness of data analysis techniques; suitability of facilities; training, experience, and research competence of investigators; and soundness of proposed budget.

V. METHOD OF APPLYING

Applicants are asked to notify the Demographic and Behavioral Sciences Branch, NICHD (See address below) at least one month prior to formal submission of an application. Include name of principal investigator, institutional address, title of application, and abstract of proposed research. Indicate that the application is in response to this RFA. When preparing the formal application, use form 398 (Rev. 5/82) for the individual research projects and the NIRAs. If your institution does not have this application booklet, copies may be obtained from:

Office of Grant Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7441

In order to identify the application as being in response to this RFA check "yes" on item 2, page 1, of the application form and enter the title **"Antecedents and Consequences of Volumtary Contraceptive Sterilization"** and the RFA number. A cover letter repeating that this application is in response to the RFA of the NICHD, DBSB, will expedite the routing of the application.

Send or deliver the completed application and six (6) signed, complete copies of it to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

Applications must be received by December 15, 1983. An application which is not received by this date will be considered ineligible and returned.

VI. TIMETABLE

Application receipt date - December 15, 1983

Initial review date - February/March 1984

Review by National Institute of Child Health and Human Development Advisory Council - June 1984

Anticipated award date - July 1, 1984

Inquiries regarding this announcement may be directed to:

Sidney H. Newman, Ph.D.
Behavioral Scientist Administrator
Demographic and Behavioral Sciences Branch
National Institute of Child Health and
Human Development
Landow Building - Room 7C25
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1174

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NICHD-CR-83-2

REPRODUCTIVE DISORDERS

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: October 17, 1983

I. BACKGROUND

The Reproductive Sciences Branch (RSB), of the Center for Population Research (CPR), of the National Institute of Child Health and Human Development (NICHD), is inviting research grant applications for investigations in selected topics in Reproductive Medicine. By issuing a Request for Applications (RFA), CPR is indicating its intention to encourage investigator interest in specific research areas important to its mission, and currently not supported at levels appropriate to the health care of women.

The RSB supports research dealing with the biomedical basis of reproduction and its application to patient care. Reproductive Medicine, one of the four programs of the RSB, funds research into the clinical implications of that information, encompassed in two subdivisions, Human Infertility and Reproductive Disorders. Reproductive Disorders is concerned with the studies of selected impairments or modifictions of human reproductive systems which are recognized disease entities. This RFA will be restricted to studies in Reproductive Disorders. Excluded is research in malignant conditions, infectious disease and the aging process, supported by other Institutes of the National Institutes of Health (NIH).

II. RESEARCH GOALS AND SCOPE

The purpose of this RFA is to encourage clinicians and other biomedical and behavioral scientists to conduct investigations aimed at the alleviation of selected human reproductive tract disorders known to cause significant morbidity and/or progressive impairment of reproductive capacity. Since these disturbances, many of them common in occurrence, are at times marked by recurrent physical suffering and may eventuate in the need for distressing, costly and temporarily incapacitating infertility management protocols, there seems to be clear reason to encourage investigation in their optimal management.

Among possibly useful approaches to investigation are the following:

1. studies of pathophysiology and disturbed biological mechanisms;
2. applications of new modes of investigation, such as immunoreactivity, laparoscopy and hysteroscopy, ultrasonography, imaging techniques employing magnetic resonance, hormone-receptor interactions;

3. delineation of the natural course of disease; and
4. studies of behavioral concomitants of disease and their implications.

The research areas for which applications are sought with this RFA are described below:

A. Disturbances in hypothalamic-ovarian function

As knowledge of normal endocrine relationships in the female reproductive system has grown, physicians have found it possible to apply increased specificity to the characterization of menstrual abnormality during reproductive life. In some cases this has led to recognition of increased importance of clinical entities, and to redefinition of others. Among such disorders the following are deemed of special importance:

1. Hypothalamic amenorrhea is a common diagnosis of exclusion made in young women. Mechanisms underlying its relationship to environmental stress and its long-term implications to impaired fertility are uncertain.
2. Amenorrhea associated with high levels of physical exercise or with weight reduction associated with anorexic syndromes has become increasingly common. In both instances, fundamental pathophysiology warrants further study.
3. Polycystic ovarian disease needs sharpened definition as a clinical entity, and data pertaining to its several hypothetical causations, as well as study of its impact on extended reproductive performance, are required.
4. Luteal phase defect appears to be part of the basis of menstrual dysfunction and relative infertility in some women. Its management would benefit by clarification of diagnostic criteria, its impact on long term reproductive capacity and efficacy of treatment.
5. Premature ovarian failure shortens reproductive life through the interplay between genetic and environmental factors. Techniques for its prediction, early recognition and prevention are important.

B. Endometriosis

External endometriosis is, for many women, a progressively discomforting disease, at times crippling and life threatening, associated with behavioral alterations and infertility. Adenomyosis, a common concomitant of and/or indication for hysterectomy is associated with pelvic pain, altered menses and possibly impaired fertility. Evaluation of pain syndromes, objective indicators of impaired function, and adequacy of fertility-preserving treatment remain important problems.

C. Ectopic Pregnancy

Increasing in incidence, extrauterine gestation carries acute risks. The hazard of spontaneous and/or surgical tubal destruction and the likelihood of pelvic peritoneal scarring with impaired fertility represent jeopardy to reproductive capacity in the long term. The occurrence of ectopic pregnancy after tubal reparative surgery, an increasing concern, underscores the need for investigation. Detailed knowledge of the mechanisms underlying external migration of the ovum, endosalpingiosus and tubal diverticulae remains imperfect.

III. MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional grant-in-aid (R01). The receipt date for this single-competition announcement is October 17, 1983. The earliest requested start date for grants would be July 1, 1984. Applications will be reviewed in competition with each other, and it is anticipated that 10-12 grants will be awarded under this program.

IV. REVIEW PROCEDURES AND CRITERIA

A. Procedures

Research grant applications should be submitted on form PHS 398, and labelled in item 2 of the face page "In Response to RFA NIH-NICHD-CR-83-2." This form is available in most institutional business offices or from the Division of Research Grants (DRG), NIH. Applications will be reviewed by NIH staff for responsiveness to the RFA. Applicants judged to have submitted a non-responsive application will be contacted and given an opportunity to withdraw the application, or to have it assigned for review in the same manner as unsolicited grant applications. A proposal submitted in response to this RFA identical to a research grant application already submitted to NIH for review, is not acceptable for this RFA.

Applications submitted in response to this RFA will be reviewed for technical merit by an initial review group convened by the DRG solely to review these applications. The National Advisory Child Health and Human Development Council will review the applications in June 1984.

B. Review Criteria

Criteria for evaluation by the initial review group will be the same as for other research grant proposals. They are as follows:

1. scientific merit--the significance of proposed questions, research design, methodology, data analysis and interpretation;

2. research experience and competence of the applicant(s);

3. adequacy of time and effort dedicated to the project by investigators and staff;

4. adequacy of collaborative relationships, if applicable;

5. adequacy of existing and proposed facilities and resources; and

6. costs in relation to scope of the project.

V. METHOD OF APPLYING

Applications should be submitted on form PHS 398. The conventional mode of preparation should be employed. The original and six (6) copies should be received by the DRG no later than October 17, 1983. Applications should be directed to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

In addition to those mailed to the DRG, three (3) copies of the application should be sent to:

Thomas Kirschbaum, M.D.
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health and
Human Development
National Institutes of Health
Landow Building - Room 7C33
Bethesda, Maryland 20205

Telephone: (301) 496-6515

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NICHD-CPR-83-3

HUMAN FEMALE INFERTILITY

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: October 17, 1983

I. BACKGROUND

The Reproductive Sciences Branch (RSB) of the Center for Population Research (CPR) of the National Institute of Child Health and Human Development (NICHD) is inviting research grant applications for investigations in selected topics in human infertility. By issuing a Request for Applications (RFA), CPR is indicating its intention to encourage investigator interest in specific research areas important to its mission and currently not supported at levels appropriate to the health care of women.

The RSB supports research dealing with the biomedical basis of reproduction and its application to patient care. Reproductive Medicine, one of the four programs of the RSB, funds research into the clinical implications of that information, encompassed in part in human infertility. Infertility is defined as the inability of couples to reproduce as they wish.

Concern for human infertility lies within the purview of CPR and has been designated an area of high priority for research support by NICHD. Increasing numbers of couples are presenting to physicians with complaints of infertility, and the diagnosis and management of such problems has become a significant concern of Americans. New research methodologies have expanded investigative opportunities in this area. A vigorous research effort is essential to continued progress.

This RFA will be restricted to studies in the biologic basis for infertility in women and the evaluation and management of such problems. Similar investigations in the male and interrelationships between male and female reproductive functions will be the subject of subsequent RFAs. Excluded is research in malignant conditions, infectious diseases, and the aging process supported by other Institutes of the NIH.

II. RESEARCH GOALS AND SCOPE

There is a compelling general need in research in human infertility for studies of normal reproductive tract function, of the natural history of disturbances of function, and for controlled observations of interventions obtained through rigorous application of the scientific method. Several areas of particular interest and concern have been defined but do not constitute an inclusive list of topics appropriate for research in human infertility.

A. Normal Ovarian Cycle

Clinical investigation of infertile couples has rapidly incorporated new investigative techniques. As examples, ultrasonic pelvic scanning has been employed to estimate the number and size of maturing ovarian follicles, positron emission tomography has been used to follow changes in pelvic architecture with time, and follicle aspiration has disclosed evidence of polyovular ovarian follicles. There is need to characterize the normal ovarian cycle through studies in couples of unquestionable fertility with respect to changes in the reproductive tract discerned by ultrasound and other imaging techniques, by endoscopy, and by the measurement of biologically active materials in blood and other body fluids.

B. Immunology

The role of immunoreactivity in human reproduction and immunologic aspects of reproductive failure continue to comprise important directions for new research. Study of the mechanisms by which the human conceptus is rendered immunologically privileged from rejection have important implications both to infertility and/or early reproductive failure. Failure of development of blocking antibodies or of locally produced hormonal immunosuppression as by progesterone may be manifest clinically as infertility, spontaneous abortions, congenital anomalies, or later as pregnancy-induced hypertension or intrauterine growth retardation. The apparent role of HLA compatibility between mates in diminishing reproductive capacity warrants further research, both as to its significance in clinically defined infertility and to operant mechanisms. Further exploration of multipartite agents such as early pregnancy factor (EPF), a possibly very potent immunosuppressant requiring contribution from ovarian follicle, tube, and zygote as well as pituitary prolactin, is desirable. The nature of the apparent relationship between thymic and ovarian function deserves investigation.

C. Human LHRH Agonists

The availability of LHRH agonists provides an important tool in the investigation, differential diagnosis and possible treatment of endocrine related causes of infertility in women. Exploration of their usefulness of these agents in humans and other mammals seems appropriate.

D. Oocyte Development and Release

Research in oocyte selection, maturation and release has become increasingly important as has the study of patterns of hormone secretion and concentration during normal and abnormal ovarian cycles. Abnormalities in such patterns and altered relationships between ovarian and endometrial cycles may account for some cases of unexplained infertility. There is continued need for an inexpensive, easy to use means of detecting ovulation, employing urine, blood, saliva or other biological substances. Such a technique would be useful in the appraisal of infertility, in the evaluation of treatment, and in periodic abstinence for reproductive control.

E. Androgens

There is need to evaluate the role of androgens in follicle development, oocyte maturation, ovulation, and implantation. Atypically excessive androgen exposure may render the endometrium incapable of normal implantation mechanisms. Methods effective in diminishing the impact of androgen-induced modifications of normal female reproductive functions are needed.

F. Tubal Function

The detailed mechanics of modulation of uterine tubal function by sex steroids, prostaglandin species, neurotransmitters and proteins requires further elucidation, as does the effect of prostaglandin synthetase inhibitors and other antagonists on tubal mechanics. The possible roles of these and other substances produced by the uterus in normal and disturbed tubal function have been incompletely explored.

Technical developments have enabled the possible study of the nutrient uptake and requirements of the preimplantation embryo in tubal and uterine fluids, and such research has potential importance to the study and treatment of human infertility.

The increasing performance of restoration procedures following surgical tubal sterilization makes exploration of optimal surgical approaches important. Similarly, investigation into the prevention of subsequent ectopic pregnancy and other forms of reproductive wastage has general interest.

G. The Cervix

The biochemical characterization of cervical mucus continues to be important to understanding its role in human infertility, both in terms of sperm transport and its possible role in maintaining the intrauterine environment prior to implantation. Studies of the impact of prior cervical surgical procedures, including conization and multiple biopsy, and of spontaneously occurring cervical stenosis on sperm transport and implantation have importance to the evaluation of infertile couples.

III. MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional grant-in-aid (R01). The receipt date for this single-competition announcement is October 17, 1983. The earliest requested start date for grants would be July 1, 1984. Applications will be reviewed in competition with each other, and it is anticipated that 10-12 grants will be awarded under this program.

IV. REVIEW PROCEDURES AND CRITERIA

A. Procedures

Research grant applications should be made on form PHS 398, and labelled in item 2 of the face page "In Response to RFA NIH-NICHD-CPR-83-3." This form is available in most institutional business offices or from the Division of Research Grants (DRG), NIH. Applications will be reviewed by NIH staff for responsiveness to the RFA. Applicants judged to have submitted a non-responsive application will be contacted and given an opportunity to withdraw the application or to have it assigned for review in the same manner as unsolicited grant applications. An application will be considered unresponsive to this RFA if it is identical to one already submitted to the NIH for review.

Applications submitted in response to this RFA will be reviewed for technical merit by an initial review group convened by the DRG solely to review these applications. The National Advisory Child Health and Human Development Council will review the applications in June 1984.

B. Review Criteria

Criteria for evaluation by the initial review group will be the same as for other research grant proposals. They are as follows:

1. scientific merit—the significance of proposed questions, research design, methodology, data analysis and interpretation;
2. research experience and competence of the applicant(s);
3. adequacy of time and effort dedicated to the project by investigators and staff;
4. adequacy of collaborative relationships, if applicable;
5. adequacy of existing and proposed facilities and resources; and
6. costs in relation to scope of the project.

V. METHOD OF APPLYING

Applications should be submitted on form PHS 398. The conventional mode of preparation should be employed. The original and six (6) copies should be received by the DRG no later than October 17, 1983. Applications should be directed to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

In addition to those mailed to the DRG, three (3) copies of the application should be sent to:

Thomas Kirschbaum, M.D.
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health and
Human Development
National Institutes of Health
Landow Building - Room 7C33
Bethesda, Maryland 20205

Telephone: (301) 496-6515

ANNOUNCEMENT

RESEARCH GRANTS FOR CLINICAL TESTING OF ORPHAN PRODUCTS FOR RARE DISEASES

NATIONAL INSTITUTE ON AGING
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES
NATIONAL CANCER INSTITUTE
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF DENTAL RESEARCH
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES
NATIONAL EYE INSTITUTE
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

This announcement is intended to inform interested individuals of the intention of the above-listed Institutes to support the clinical testing of orphan products for rare diseases.

I. BACKGROUND

There are many diseases and conditions which affect such small numbers of individuals in this country that the diseases and conditions are considered rare. Because of development costs and a relatively small market, drugs, vaccines, and devices for the diagnosis, prevention or treatment of these rare diseases are referred to as "orphan products." Effective therapy often does not exist, although existing or experimental drugs, vaccines, or devices might prove effective in rare diseases if adequate clinical trials were to be conducted. Therefore, the above-named Institutes are encouraging submission of research grant applications for support of clinical testing of orphan products (drugs, vaccines, devices) for rare diseases or conditions. Research grants and/or contracts are available for the preliminary basic research and for the development of drugs, vaccines, and devices through the other program activities of the above Institutes and do not fall within the scope of this announcement.

II. RESEARCH GOALS AND SCOPE

The emphasis in this Program Announcement is on the clinical testing, in humans, of drugs and devices potentially efficacious in the prevention or treatment of rare diseases or conditions. Clinical testing can include evaluation of toxicity and/or efficacy. Submitted applications should therefore specifically address the conceptual, experimental, and ethical problems of clinical testing in situations in which the total patient population may be very small. Criteria for patient entrance into the trial, including but not limited to criteria for diagnosis of the rare disease or condition, should be discussed. If a multicenter study is proposed, procedures for ensuring uniform diagnosis and adherence to a common protocol should also be discussed. Realistic projections of the rate of patient acquisition should be presented. The application should also discuss existing information about the orphan product such as pharmacology and toxicity data in animals and/or man, existing clinical evidence for efficacy, etc.

III. MECHANISM OF SUPPORT

The mechanism of support for this activity will be the research grant, awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended, 42 USC 241). The regulations (Code of Federal Regulations, Title 42 Part 52, and Title 45 Part 74) and policies which govern the research grant programs of the National Institutes of Health (NIH), will prevail. This program is not subject to Health Systems Agency review.

The award of grants pursuant to this announcement is contingent upon availability of appropriated funds.

IV. METHOD AND CRITERIA OF REVIEW

Applications will be received by the NIH's Division of Research Grants (DRG), referred to an appropriate study section for scientific merit review, and assigned to individual Institutes for possible funding. These assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines.

Applications in response to this announcement will be reviewed in nationwide competition, and in accordance with the usual NIH peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (study section). Following this review, the applications will be evaluated by the appropriate Institute National Advisory Council. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

V. APPLICATION PROCEDURES

A. Deadline: Applications will be accepted in accordance with the usual dates for new applications:

APPLICATION RECEIPT	INITIAL REVIEW	COUNCIL REVIEW	EARLIEST START DATE
Nov. 1	Feb./March*	May*	July 1*
March 1	June	Sept./Oct.	Dec. 1
July 1	Oct./Nov.	Jan./Feb.*	April 1*

* of the year following application receipt.

B. Method of Applying: Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions orfrom the DRG. To identify the application as a response to this announcement, check "yes" in item 2 of page of the application and enter the title "NIH ORPHAN PRODUCT PROGRAM ANNOUNCEMENT."

The original and six copies of the application should be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

For further information, investigators are encouraged to contact one or more of the following individuals at the NIH:

NATIONAL INSTITUTE ON AGING

Dr. Alan L. Pinkerson
Deputy Associate Director for Planning
and Extramural Affairs
National Institute on Aging
National Institutes of Health
Building 31 - Room 5C06
Bethesda, Maryland 20205

Telephone: (301) 496-9322

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Dr. George J. Galasso
Development and Applications Branch
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 750
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7051

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Dr. John E. Nutter
Office of Program Planning and Evaluation
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Building 31 - Room 7A17
Bethesda, Maryland 20205

Telephone: (301) 496-6752

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Dr. Benjamin T. Burton
OPA and SC
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
Building 31 - Room 9A03
Bethesda, Maryland 20205

Telephone: (301) 496-4955

NATIONAL CANCER INSTITUTE

Dr. Saul S. Schepartz
Division of Cancer Treatment
National Cancer Institute
National Institutes of Health
Building 31 - Room 3A51
Bethesda, Maryland 20205

Telephone: (301) 496-6404

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Dr. Duane F. Alexander
Deputy Director
National Institute of Child Health and
Human Development
National Institutes of Health
Building 31 - Room 2A04
Bethesda, Maryland 20205

Telephone: (301) 496-1848

NATIONAL INSTITUTE OF DENTAL RESEARCH

Dr. James P. Carlos
Associate Director, National Caries Program
National Institute of Dental Research
National Institutes of Health
Westwood Building - Room 528
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7239

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Dr. Rajendra S. Chhabra
National Institute of Environmental
Health Sciences
National Institutes of Health
P.O. Box 12233
Building 101, Mail Drop D4-02
Research Triangle Park, North Carolina 27709

Telephone: (919) 629-3386

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Dr. William M. Kluwe
Pharmacologist
National Institute of Environmental
Health Sciences
National Institutes of Health
P.O. Box 12233 - D442
Research Triangle Park, North Carolina 27709

Telephone: (919) 541-4177

NATIONAL EYE INSTITUTE

Dr. Douglas Gaasterland
Chief, Glaucoma Section, Clinical Branch
National Eye Institute
National Institutes of Health
Building 10 - Room 10D11
Bethesda, Maryland 20205

Telephone: (301) 496-4050

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Dr. Sara A. Gardner
Director, Pharmacological Sciences Program
National Institute of General Medical Sciences
National Institutes of Health
Westwood Building - Room 919
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7181

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Dr. Thomas L. Robertson
Special Assistant to the Director
National Heart, Lung, and Blood Institute
National Institutes of Health
Building 31 - Room 5A35
Bethesda, Maryland 20205

Telephone: (301) 496-3245

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Dr. F.J. Brinley, Jr.
Director, Convulsive Developmental and
Neuromuscular Disorders Program
National Institute of Neurological and
Communicative Disorders and Stroke
National Institutes of Health
Federal Building - Room 812
Bethesda, Maryland 20205

Telephone: (301) 496-6541

ANNOUNCEMENT

BEHAVIORAL/BIOMEDICAL INTERDISCIPLINARY RESEARCH TRAINING

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Dates: October 1, February 1, June 1

I. INTRODUCTION

The Center for Research for Mothers and Children (CRMC), of the National Institute of Child Health and Human Development (NICHD), invites applications for National Research Service Awards (NRSA), (both individual postdoctoral fellowships (F32) and institutional training grants (T32) for pre- and postdoctoral trainees) in support of training individuals for research in the interdisciplinary areas of behavior and biomedicine.

II. BACKGROUND AND SCOPE

The research mission of the CRMC encompasses the study of development from conception to adulthood. Interdisciplinary research among biomedical specialties has been instrumental in discovering many of the basic biological mechanisms underlying development. In order to understand the complex interactions between those mechanisms and the behavioral determinants of development, scientists must learn the basic principles and methods used in both behavioral and biological research. The NICHD encourages applications for such interdisciplinary research training. Among the research fields relevant to this announcement are developmental behavioral genetics, behavioral pediatrics, developmental behavioral pharmacology, behavior and nutrition, and developmental behavioral biology (especially neurobiology and neuroendocrinology).

Some examples of research within the domain of the Center's mission that would benefit from an experimental biobehavioral approach to development are:

- Studies of the relationship between hormone levels and development of gender-specific behaviors and social interactions.
- Studies of brain/behavior relationships including electrophysiological, anatomical and biochemical correlates of language, perception, memory, and sensory/motor development.
- Studies of temperament, learning, and sensory development in relation to genetics.

This program is described in the Catalog of Federal Domestic Assistance No. 13.895, Research for Mothers and Children. Awards will be made under authority of Section 472 of the Public Health Service Act as amended (42 USC 2891-1). Title 42 of the Code of Federal Regulations, Part 66, is applicable to these awards. This program is not subject to Health Systems Agency review.

- Studies in behavioral development consequent to pre- and postnatal exposure to drugs and to toxic agents related to lifestyle (e.g., cigarette smoke, alcohol, lead).

- Studies of biological and molecular substrates and correlates of developmental delays, learning disabilities, and mental retardation.

- Studies of biological and behavioral factors in children relevant to prevention and treatment such as health promotion, illness behavior, risk taking, compliance with medical regimens, and biofeedback.

- Studies of the relationship of early experience and the environment to the etiology of mental retardation and other developmental disabilities.

- Studies of behavior and nutrition (e.g., failure to thrive, obesity, learning deficits, hyperactivity, anorexia, control of appetite and satiety, and nutritional factors in brain/behavioral development).

III. TRAINING GOALS

The Center wants to encourage the biobehavioral, interdisciplinary approach to the study of development and believes that the initiation and conduct of such research would be facilitated by increased emphasis on the interdisciplinary training of individuals at an early stage of their research careers. Thus, applicants trained in a biomedical discipline may wish to add the measures, methods and knowledge base of the behavioral sciences to their biomedical repertoire by proposing individual postdoctoral training under the sponsorship of scientists qualified to offer and direct appropriate research training. Conversely, individuals with research interests and educational backgrounds in areas of behavioral development may propose training in any of the biological sciences or medical specialties so as to become familiar with the theories and research methods of the biomedical disciplines. Similarly, institutions applying for interdisciplinary training grants under this announcement should propose training programs, curricula, and staff designed to offer pre- and postdoctoral trainees the opportunity for such multidisciplinary, biobehavioral training. The training environment should facilitate such training as evidenced by interdepartmental cooperation in terms of faculty, required course work and guidance of trainee research.

The goal of the training is to produce investigators with knowledge of the concepts and methodologies of behavioral science and of biomedical disciplines. The training, both formal and experiential, should be of sufficient depth to enable the investigator to formulate research projects which encompass concepts, tools, and methods of both behavioral and biomedical disciplinary areas.

IV. MECHANISM OF SUPPORT

Support for this training will be through the NRSA.

V. APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on form PHS 6025 for institutional training grants (T32), or on form PHS 416-1 for individual postdoctoral fellowships (F32). Application kits are available from most institutional business offices, or they may be obtained from the DRG, at the address given below. Application kits contain instructions and information regarding eligibility requirements, selection of awardees, stipends and other allowable training costs, review cycles, submission deadlines, review criteria, and payback requirements. In addition to the review criteria specified in these instructions **(NIH Guide for Grants and Contracts, Special Edition, Vol. 11, No. 7, June 18, 1982, p. 7)**, applicants for both institutional and individual training, and their qualifications for funding under this training initiative, will be judged upon the more specific criteria listed below.

Applications must be responsive to this program announcement and relevant to the goals of the NICHD. Applications not responsive or which focus on areas of primary interest to another Institute will be assigned to the appropriate Institute by DRG. For institutional training grant applicants, qualifications for funding under this training initiative will be judged upon the following criteria:

- Appropriate required training in fundamental principles and methods of both the behavioral and the biomedical sciences.
- Quality of laboratory research experiences in both behavioral and biomedical settings.
- Faculty and facilities sufficient to meet the needs of the training program.
- Individual research project requirements.

Individual applications for interdisciplinary training (F32) must be made in accordance with this program announcement and with the goals of the NICHD. The individual grant awards will be evaluated on the basis of the following criteria:

- The scientific merit of the proposal relative to training the applicant for interdisciplinary behavioral/biomedical research.
- Qualifications of the applicant and appropriateness of the proposed training.
- Expertise and qualifications of the proposed sponsor.
- Adequacy of resources and facilities.
- Appropriateness of the mix between formal course work and laboratory orclinical experience.

An initial review will be made by an appropriate NIH review group. Institutional training grants will receive a second-level review from a National Advisory Council. For individual postdoctoral fellowships, an Institute staff committee will provide a second review. The phrase "NICHD Behavioral/Biomedical Research Training Announcement" should appear in space 1B on form PHS 6025, and in space 2 of form PHS 416-1. The original and six copies of the application should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

Two copies of the application should be mailed to:

Duane F. Alexander, M.D.
Deputy Director
National Institute of Child Health
and Human Development
National Institutes of Health
Building 31 - Room 2A04
Bethesda, Maryland 20205

Telephone: (301) 496-1848

ANNOUNCEMENT

SURGICAL ONCOLOGY RESEARCH

NATIONAL CANCER INSTITUTE

The National Cancer Institute's (NCI) Division of Cancer Treatment (DCT) desires to expand support of surgical oncology research. This announcement invites applications for individual research project (R01) and program project (P01) grants.

I. BACKGROUND

The treatment of cancer has evolved as a multidisciplinary effort involving (but not limited to) the disciplines of surgical oncology, medical oncology, pediatric oncology, and radiation oncology. The disciplines of medical oncology, pediatric oncology, and radiation oncology have developed strong cadres of academic investigators but academic development in surgical oncology has not kept pace. It is felt that surgical oncology is not keeping pace because of an insufficient number of surgical oncology research programs and an insufficient number of surgeons undertaking research related to cancer. Continued development of multidisciplinary treatment of cancer is the long range objective of the DCT and the attainment of the goal requires sufficient academic strength in surgical oncology.

II. GENERAL CONSIDERATIONS

The NCI's DCT is seeking applications for research grants concerned with research in surgical oncology. Examples of relevant studies include mechanisms of metastases, effect of surgery on tumor cell kinetics, and host responses to surgery. Preclinical and clinical research is encompassed in this program. Categories of research include (but are not confined to) the following:

A. Pathophysiologic studies in laboratory models or in humans related to surgery and cancer.

B. Laboratory and clinical studies which examine the biochemical, cytokinetic, immunological, or nutritional effects of cancer surgery.

C. Therapeutic studies in which surgery or a surgical question is the primary treatment modality.

D. Studies relevant to staging of patients and identifying prognostic factors relevant to the treatment of cancer patients.

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended; 42 USC 282) and administered under PHS grant policies and Federal Regulations: 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

E. Surgical supportive care.

F. Regional chemotherapy or hyperthermia in which a surgical approach to the treatment site is a major aspect of the procedure.

In making this program announcement it is not the intent of the NCI to make or imply any delimitation of investigator-initiated research in the cancer field.

III. APPLICATION PROCEDURE

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions or from the Division of Research Grants, NIH. The title "Surgical Oncology Research" should be typed in section 2 of the first page of the application. Additionally a brief covering letter should accompany the application indicating it is being submitted in response to this program announcement.

The original and six copies of the application should be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

In order to alert the DCT to the submission of the proposals with primary thrust directed to surgical oncology research, a copy of the covering letter and an additional copy of the application should be sent under separate cover to:

Ernest V. deMoss, M.D., M.P.H.
Head, Surgery Section
Clinical Investigations Branch
Division of Cancer Tretment
National Cancer Institute
Landow Building - Room 4B04
Bethesda, Maryland 20205

Telephone: (301) - 496-4844

In addition, for P01 grant applications, two complete copies should be sent under separate cover to the following address:

Referral Officer
Grants Review Branch
Division of Extramural Activities
National Cancer Institute
Westwood Building - Room 826
Bethesda, Maryland 20205

IV. REVIEW PROCEDURES AND CRITERIA

Applications in response to this announcement will be reviewed on a nation-wide basis in competition with each other, and in accord with the usual NIH peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants. Following this initial review, the application will be evaluated for program relevance by the National Cancer Advisory Board.

Where applicable to a particular project review criteria will consist of the following:

1. Relevance of the project to surgical oncology research and to the national cancer effort.
2. Feasibility of reaching the proposal's objectives.
3. Significance and adequacy of pilot data to the proposal's objectives.
4. Qualifications of the principal investigator and supporting personnel to achieve the project goals.
5. Adequacy of core facilities and basic equipment to support the project.
6. Availability of suitable patient and control populations if required.

For further information regarding this announcement and the review criteria for the P01 grant application and the R01 grant application, investigators are encouraged to contact Dr. Ernest V. deMoss at the address and telephone number given above. Before submitting a P01 application, please discuss a letter of intent with Dr. deMoss.

ANNOUNCEMENT

SPECIAL PROGRAM AREAS OF INTEREST

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

The National Institute of Environmental Health Sciences (NIEHS) is the principal Federal agency for biomedical research on the effects of chemical, physical and biological environmental agents on man's health and well being. The Institute supports efforts to identify potentially hazardous environmental agents, including the development, testing, and validation of biological test systems which can be used to measure and predict human toxicity from exposure to environmental factors. The purpose of this general Announcement is to summarize those areas of research considered important to the Institute, as follows:

ALTERNATIVE DESIGNS OF STANDARD CANCER BIOASSAY

The objective is to stimulate interest in the development of alternative designs of the standard cancer bioassay in order to make the end results more amendable to low-dose extrapolation and risk estimation. Alternative designs should maintain the cancer screening potential of the current bioassay.

STUDIES RELATING HUMAN HEALTH EFFECTS TO PBB

The objective is to provide information which will aid in the assessment of the real and potential dangers to man from exposure to commercial preparations of PBB's. Areas of research currently of interest should emphasize information relative to toxicity of PBB congeners for humans, including storage, metabolism and excretion, additive, synergistic or otherwise interactive reactions with other pollutants, studies of immune functions in populations exposed to PBB's, studies of immune functions in populations exposed to PBB's, development of means for clearing the body of PBB's and similar compounds and central nervous system manifestations in children exposed to PBB.

IMMUNOTOXICOLOGY OF ENVIRONMENTAL AGENTS

The objective is to stimulate high quality research in areas of immunotoxicology including applications of immune function tests, changes in immune response following exposure to environmental chemicals, development of immunologic models to study hypersensitization and allergy, and the effects of inhalation exposure on immune elements in the lung.

BIOLOGICAL EFFECTS OF CHEMICAL INTERACTIONS

The objective is to study all facets of biological effects of interactions of chemicals of environmental concerns. Of particular interest are projects aimed at developing new methods for study of interactions.

ENVIRONMENTAL MEDICINE

The objective is to generate interest in the use of laboratory or clinical tests that aid in the detection and measurement of toxicity demand from chemical exposure at levels which do not produce acute symptoms but which may produce detectable damage years later. Of particular interest are the effects of exposure that may occur in occupational settings, therapeutic levels of unexpected episodes of chemical exposure such as might occur with populations exposed to hazardous chemical wastes. The details of the individual programs can be obtained from:

Dr. Edward Gardner
Program Director
Regular Research Program Section
Scientific Programs Branch, Extramural Program
P.O. Box 12233
Research Triangle Park, N.C. 17709

I. REVIEW PROCEDURES AND CRITERIA

A. Review Procedure

Applications received in response to this announcement will be considered along with other non-solicited applications and will be assigned in accordance with the NIH Referral Guidelines. The initial review will be for scientific merit and will be carried out by an appropriate peer review group. The secondary review for relevance and responsiveness to the announcement will be made by the appropriate National Advisory Council.

B. Review Criteria

The factors considered to be important for review include a demonstrated knowledge of the applicable science, adequacy of facilities and commitment, availability of subject population when applicable and in-depth knowledge of the state-of-the-art to which the announcement is directed. The application will be judged upon the overall scientific merit, adequacy of methodology, facilities and resources, commitment of time and cost effectiveness of the proposal. The sponsoring institution should indicate a commitment of facilities and resources to the program.

II. METHOD OF APPLYING

Applications should be submitted on form PHS 398, the application for the traditional research grant. Application kits containing this form and the necessary instructions are available in most institutional business offices or from the Division of Research Grants (DRG), NIH. Applications must be sent to the following:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

This program is described in the Catalog of Federal Domestic Assistance, No. 13.112, Characterization of Environmental Health Hazards; 13.113, Biological Response to Environmental Health Hazards; 13.114, Applied Toxicological Research and Testing; and 13.115, Biometry and Risk Estimation. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

ANNOUNCEMENT

DRUG ABUSE PREVENTION RESEARCH

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

NATIONAL INSTITUTE ON DRUG ABUSE

I. INTRODUCTION

The purpose of this announcement is to stimulate investigator interest in certain areas of prevention research which are of particular importance to the national drug abuse research program. Understanding of the drug abuse phenomenon has increased greatly over the past decade. Nevertheless, there remains a great deal to be learned. In particular, we need to develop and evaluate effective means of preventing the onset and habitual non-medical use of drugs. Research is needed to refine prevention intervention techniques and to develop and refine interventions targeted for specific groups at risk of drug abuse. Additional research is needed on factors which increase individuals' risk of drug abuse, and on factors which tend to make some individuals invulnerable to drug abuse. Research on risk factors and invulnerabilities must consider the implications for developing or refining preventive interventions. Background and guidance for research proposals in these areas are provided in this announcement.

II. OVERVIEW

The Department of Health and Human Services (DHHS) has launched a major health promotion initiative to improve the health of the American people. Specific health objectives have been established for reducing death and disability for fifteen areas, including misuse of alcohol and drugs. In keeping with the Department's overall thrust and the Institute's assessment of national needs, the National Institute on Drug Abuse (NIDA) is supporting a broad-based drug abuse prevention research program which includes research on (1) primary disease prevention and health promotion interventions aimed at reducing the incidence of drug abuse, (2) outreach and early intervention programs for novice drug users and abusers who have not been clinically identified, (3) methods for early identification and screening of persons at risk of drug abuse, and (4) risk factors as a basis for the design of preventive interventions.

Research supported under this announcement is intended to further the development of prevention intervention theories and technology. Intervention research must go beyond the evaluation of a specific program. Intervention research should have a carefully developed theoretical component, or should test a

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This program is described in the Catalog of Federal Domestic Assistance No. 13.279, Drug Abuse Research Programs. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

number of assumptions which will lead to new theories to guide intervention programs. Thus, the intervention must be based on scientific evidence about the etiology of drug abuse disorders. An additional goal is to develop intervention models which are replicable in other communities. Risk factor research must occur within the context of theory development applicable to preventive interventions. The intended focus here is to explore and clarify the role of identified risk factors in the onset of drug abuse behaviors and to consider their implications for the design or refinement of preventive interventions. (Etiological research which is outside the scope described in this announcement is also supported by NIDA's Prevention Research Branch. Investigators interested in such research should submit applications under the Institute's general Research Grants Program announcement.)

An important task in both intervention and risk factor research concerns identifying subpopulations at risk of drug abuse. Existing prevention theories have tended to focus on categories of drug users, typically distinguished by their stage in the life cycle or the particular drug which is being used. In risk factor research reliance on drug or age-group categories of users tends to minimize the importance of similarities among various user groups or various drugs or even various potentially addictive behaviors such as smoking, drinking, overeating, and gambling. Furthermore, in intervention research drug or age-group categories are not sufficiently specific to target interventions in accord with the participants' needs. Thus, an important step in intervention and risk factor research would be to distinguish specific subpopulations under study, going beyond distinctions of age or drug of abuse.

NIDA, along with the National Institute on Alcohol Abuse and Alcoholism, (NIAAA),is interested in applications which address issues common to the problems of alcohol and drug abuse. These would include, for example, studies of commonalities and differences in risk factors and common approaches, where appropriate, to the prevention of alcohol and drug abuse. Such applications may be funded jointly by both Institutes or funded solely by one Institute, depending on the emphasis.

While much of NIDA's drug abuse prevention effort is focused on adolescents, other groups in the life cycle, such as children of addicts, individuals in high risk occupations, housewives, and the elderly, also are of interest. Because of the paucity of prevention research focused specifically on ethnic minorities and the distinct needs of these populations, drug abuse among ethnic minorities is of special concern. Thus, research focused on minority populations found to be at high risk for drug abuse is espcially encouraged.

III. SUGGESTED AREAS OF STUDY

The following topics are provided as examples of areas that might be studied. Investigators are encouraged to consider any of these as well as related studies which might have value.

A. Intervention Research

The intervention process is only partially understood, and it appears unlikely that one single approach will work equally well with different groups. Research is needed to determine the effectiveness of intervention programs appropriate to specific target groups and specific drug abuse problems. In intervention research, drug use behaviors and attitudes toward use should be primary outcome measures. However, it is essential that multiple outcome measures (e.g., school performance, personal goals and expectations, attitudes, and beliefs) and their interrelationship be considered.

Adolescents have been studied extensively and two important influences have been found. One is the parental/family influence, and it has led to activities such as parent/family skills training, family therapy, and the development of parent action groups. A second major influence comes from peer pressure. Some work has focused on teaching adolescents to resist undersirable peer pressure.

Further research in areas involving the family and/or peers is encouraged. Especially high priority is placed on research on:

1. parent/family skills training approaches which develop communication and limit-setting skills, and

2. school-based programs which develop skills in resisting peer pressures to use drugs. Issues pertaining to school-based programs which warrant special attention include the applicability of specific approaches to different sub-populations, the role of peer leaders in program implementation, and the importance of follow-up interventions to sustain program effects.

Research on brief community interventions is also encouraged. One suggested approach is to attach an evaluation component to a community program proposed or already in progress, such as a mass media campaign focused on a specific drug abuse problem. Research questions could deal with factors such as the content of the message, its type of delivery, its intent and its effect. A second approach is small scale field studies of community organization efforts by natural groups in the community, for example, a senior high school class which alters the school environment or a parent's group which alters the community environment to discourage drug use.

While intervention research focused on adolescents is a primary interest, there is also a need for more research on intervention approaches for other groups in the life cycle found to be at risk.

B. Methodology development

There is a need to develop new research protocols and methods and refine existing methods which will help make more useful and valid assessments of preventive intervention efforts. The ultimate criterion of whether a reduction or cessation in drug use has occurred is desirable, but other points are important as well; for example, the cost relative to the benefits, the broad impact on the community, and outcome measurement techniques. Studies are needed to develop improved methods in areas such as these.

C. Risk factors in drug experimentation

An important task concerns identifying subpopulations at risk of drug abuse and describing the specific risk factors for each population. Studies are needed which explore risk factors and their implications for preventive interventions. Proposals for such studies must show how this knowledge sought could be used directly for developing or refining an intervention strategy.

Interpersonal risk factors associated with the beginning use of marijuana, cigarettes, or wine and beer by pre-teen and teenage children have received insufficient attention. Equally neglected is the transition from the experimental stage to the user state. The two most common foci for studies of experimentation and use of drugs have been the respective roles of parents and peers. Parents are thought to provide models through their use of tobacco and alcohol. Peers are thought to bring pressure through their insistence that one conform with the peer group's standards. By themselves these explanations are imcomplete. There is a need to know more about the circumstances under which peer and parental influences work and their specific and direct implications for prevention. Attention to the importance and efficacy of parental limit-setting and other parental behaviors is especially encouraged.

In social environments which are particularly conducive to initiating a career in drugs, there are some adolescents who are invulnerable. The special factors which lead to this desirable condition need to be explored for their intervention implications.

The role of environmental factors in the promotion of healthy behaviors and in the initiation and maintenance of drug abusing behaviors is only partially understood. There is a need for research which looks beyond the factors which place individuals at risk of drug abuse to the structural and institutional factors which affect the immediate risk factors, such as school policies and procedures or management procedures in the workplace. Research should focus on environmental factors which could reasonably be modified.

Much of the research on risk factors related to drug abuse has been focused on adolescents. Less is known about factors which place other groups in the life cycle at risk. Thus, study is encouraged which explores the risk factors associated with drug initiation among various groups.

D. Secondary data analysis

While it is anticipatd that much of the research supported under this announcement will involve the collection of original data, many prevention research questions can be addressed through the secondary analysis of large data bases which have current relevance. Such research is especially appropriate for large-sample studies which compare different populations or which explore the interrelationships among various risk factors.

IV. APPLICATION PROCEDURES

The Institute wishes to encourage investigators to submit research grant proposals in the areas discussed in this announcement. Applications may be submitted by nonprofit, for-profit, or public organizations.

The regular research grant application form PHS 398 (Rev. 5/82) must be used in applying for these awards. However, State and local agencies should use form PHS 5161 (Rev. 3/79). Application kits are available in university grant offices or from the following:

Grants Management Branch
National Institute on Drug Abuse
Parklawn Building - Room 10-25
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-6710

The original and six (6) copies of applications must be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

V. FURTHER INFORMATION AND CONSULTATION

Further information about the areas of interest described in this announcement may be obtained by contacting:

Dr. Robert J. Battjes
Chief, Prevention Research Branch
Division of Clinical Research
National Institute on Drug Abuse
Parklawn Building - Room 10A-16
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-1514

VI. REVIEW PROCEDURES

Review procedures for applications to this program conform to peer review procedures applicable to all research grants programs sponsored by the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). Applications are reviewed for scientific merit by an initial peer review group; the National Advisory Council on Drug Abuse performs a second review which may be based on policy as well as scientific merit considerations. After the Council provides final recommendations, applicants are notified of the results of the review by the Director, Officer of Extramural Policy nd Project Review.

VII. REVIEW CRITERIA

The criteria for review of applications include overall quality and scientific merit of the proposed research. Scientific merit involves considerations such as originality, feasibility, soundness of the theoretical base in relation to previous research, soundness of approach and research design and data analysis plan, as well as the qualifications and experience of the investigators. The availability of suitable facilities to perform the proposed studies, the supportive nature of the research environment, and the appropriateness of the proposed budget are also important evaluative factors. Additional criteria applicable to intervention research include appropriate commitments from and arrangements for collaboration with prevention programs and potential replicability and generalizability of the intervention.

VIII. AWARD CRITERIA

Criteria for funding of applications are based on the scientific merit of the proposal, as determined by peer review, and relevance to national need as reflected in NIDA's research priorities and plans. The availability of funds, the overall balance of the various topic areas in the program, the potential contribution of the study to the development and refinement of preventive intervention technology, and the cost effectiveness of the study also will be considered in determining which awards will be made.

ANNUAL RECEIPT AND REVIEW SCHEDULE

Receipt Dates Renewal/New	Initial Review Group	Council Meeting	Earliest Possible Start Date
Feb 1/Mar 1	June	Sept/Oct	December 1
Jun 1/Jul 1	October	Jan/Feb	April 1
Oct 1/Nov 1	February	May	July 1

IX. AVAILABILITY OF FUNDS

An estimated $1-1.5 million will be budgeted for starting new and competing renewal prevention research projects in each of the fiscal years 1984, 1985, and 1986.

X. PERIOD OF SUPPORT

Applications may request support for a period of up to five (5) years. Most projects do not exceed three years. A competing continuation (i.e., a renewal) application may be submitted before the end of project period. A competing supplemental application may be submitted during an approved period of support to expand the scope or protocol during the project period.

NIH Guide for Grants and Contracts

Vol. 12, No. 8, August 19, 1983

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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ERRATUM

ANNOUNCEMENT

PHYSICIAN SCIENTIST AWARD

NATIONAL INSTITUTE ON AGING
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF DENTAL RESEARCH
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES
NATIONAL EYE INSTITUTE
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

An Announcement in the **July 15, 1983, NIH Guide for Grants and Contracts (Vol. 12, No. 7) printed on page 7**, from the above Institutes, had an error in paragraph A under I. ELIGIBILITY. The correct paragraph A is as follows:

> A. These awards are designed to provide an intensive, supervised research experience for clinicians. Thus, candidates are restricted to those holding health professional degrees in the clinical sciences (M.D., D.D.S., D.V.M., D.O. or equivalent). Physicians holding the Ph.D. are ineligible. Candidates ordinarily will have completed at least one post-graduate year of clinical training by the time the award is made.

There is a slight change on page 13 in the title of the Director and the telephone number under the heading listed for the **National Institute of Allergy and Infectious Diseases.** The correct title and telephone number for John W. Diggs, Ph.D. is as follows:

Director, Extramural Activities Program

(301) 496-7291

NOTICE

PROGRAM PROJECT GRANT APPLICATIONS

AVAILABILITY OF REVISED NCI GUIDELINES

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH) makes a substantial commitment to the support of research through the program project grant mechanism. Approximately one-fifth of the research project support is currently provided through the program project grant. A program project grant is intended to support a broadly based multidisciplinary research program that has a well-defined central research focus or objective. The grant consists of a number of interrelated projects that contribute to the program objective. The grant may also include common supporting resources (cores) required for the conduct of the component research projects. Interrelationships between component projects result in a greater contribution to the program goals than if each project were pursued separately.

In recent years, NIH staff have noted with concern the differing concepts of what appropriately constitutes a program project. Members of the research community have expressed similar concerns, focusing primarily on the adequacy and uniformity of the peer review process for program projects. A committee of NIH staff responsible for the review process is developing new proposed guidance for agency staff and applicants. Any major changes will reflect a consensus of all institutes using the program project mechanism. Concurrently, a subcommittee of the National Cancer Advisory Board (NCAB) has studied this award mechanism in detail and has recommended the adoption of several changes in NCI's program project guidelines. In particular, the NCAB has recommended greater attention to the cohesiveness of the entire program project in the review process. The NCAB suggests that individual projects be reviewed for scientific merit not only as free-standing entities but also in the context of the program project as a whole. In this vein, some projects may be judged irrelevant to the program while other projects may be recognized as of particular value when related to the program as a whole.

NIH endorses the intent of the NCAB's recommendations and reminds prospective applicants that it is the responsibility of the principal investigator to bring together a cohesive, synergistic program focused on a central theme. Inclusion of projects which are of marginal quality or are unrelated to the program as a whole reflects poorly on the leadership of the principal investigator.

NIH is continuing to explore ways in which the review process might better ensure that individual projects are reviewed both on their own merits and as contributors to the program project as a whole. In the meantime, applicants are encouraged to structure program project applications to reflect the intended synergistic relationships of the component projects.

NCI's revised guidelines will be implemented with respect to applications received for the October 1983 deadline. Copies of the guidelines will be sent to all NCI program project grantees and to others who have indicated their intention to submit an application for the October receipt date, and will be available on request from:

Referral Officer
Grants Review Branch
Division of Extramural Activities
National Cancer Institute
2115 East Jefferson Street
Room 401
Rockville, Maryland 20852

NOTICE

SITE VISITS TO ANIMAL CARE FACILITIES

NATIONAL INSTITUTES OF HEALTH

As announced in the **June 17, 1983, NIH Guide for Grants and Contracts**, the National Institutes of Health (NIH), Office of Extramural Research and Training (OERT), has embarked on a series of ten site visits to awardee institutions to assess the adequacy of the current process for promoting proper care and use of animals in biomedical research funded by NIH. The institutions were selected randomly, one from each of the ten Department of Health and Human Services (DHHS) geographic regions within three categories of total annual NIH funding. In addition, the sample was designed to ensure that none of the ten institutions selected were among those accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). The University of Washington was among those named because at the time the selection was made NIH had not been notified that the University had received full accreditation. The site visit, however, will be conducted as scheduled even though the NIH is now aware that the University of Washington has received AAALAC accreditation.

ANNOUNCEMENT

SPECIALIZED CENTERS OF RESEARCH IN ARTERIOSCLEROSIS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The National Heart, Lung, and Blood Institute announces its intent to allow current Specialized Centers of Research (SCOR) in Arteriosclerosis to compete for designation as National Research and Demonstration Centers (NRDC). To attain this status, current SCOR grantees will have to submit a competing supplemental application that details plans for demonstration and education research activities that are thematically related to arteriosclerosis and for core activities that will serve to coordinate and integrate the various components of the NRDC.

A Request for Applications (RFA) has been issued to the current SCOR grantees in Arteriosclerosis. The application receipt date is December 1, 1983; after initial technical merit review these competing applications will be reviewed by the National Heart, Lung, and Blood Advisory Council in May 1984. The award date for successful applicants will be June 1 or July 1 and the duration of these supplemental grants will be approximately 2-1/2 years.

Although the competition is limited to current SCOR grantees in Arteriosclerosis, other interested parties may receive an informational copy of the RFA by writing to the following:

Dr. Bernard J. Krask
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 4C12
Bethesda, Maryland

The issuance of the RFA for NRDC on Arteriosclerosis does not imply any intent to discontinue support for a separate and distinct Arteriosclerosis SCOR program. The NRDC and SCOR grant mechanisms of support, together with that of investigator-initiated research, training, and contract support, represent means to promote the Institute's comprehensive research program; the support of each of these mechanisms will be continued.

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DCCP-CPCB-83-13

NEW NATURAL AND SYNTHETIC INHIBITORS OF CARCINOGENESIS

NATIONAL CANCER INSTITUTE

Application Receipt Date: November 15, 1983

The Division of Cancer Cause and Prevention (DCCP) of the National Cancer Institute (NCI) invites grant applications from interested investigators for studies on new natural and synthetic inhibitors of carcinogenesis. The proposed studies would seek, as their major objectives, to determine the extent to which inhibitors of carcinogenesis occur naturally, as in foods consumed by man, the role and potential of these substances as cancer preventive agents, their mechanisms of action, and their pharmacokinetic properties.

Grants are awarded to profit and to nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary NIH grant-in-aid, in accordance with PHS policies applicable to Research Project Grants, including cost sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to the RFA will be reviewed by the same National Institutes of Health (NIH) Initial Review Group.

The present RFA announcement is for a single competition with a specified deadline of November 15, 1983, for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

I. BACKGROUND
II. OBJECTIVES AND SCOPE
III. MECHANISM
IV. REVIEW PROCEDURES AND CRITERIA
V. METHOD OF APPLYING
VI. INQUIRIES

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law-78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

I. BACKGROUND

Strategies for cancer prevention involving reduction or elimination of human exposure to environmental carcinogens may not always be possible.

Further, significant portions of the human cancer burden may be due to endogenous carcinogens, cocarcinogens, and promoters. Inhibition of the development of cancer by administration of chemical, biochemical, and biological compounds, which directly and/or indirectly inhibit the cancer-producing effects of neoplastic and promoting substances, may offer an alternate approach to cancer prevention.

Naturally occurring substances are one of the most promising sources of these inhibitors of carcinogenesis, particularly those which are present in foods consumed by man. In this regard, epidemiologic studies have implicated diet and nutrition as important factors in the occurrence of human cancer, with both positive and negative correlations indicated for incidence or mortality at many sites with consumption of particular nutrients or food items. High intakes of legumes and cereals such as corn, rice, and beans have been associated with reduced risk for breast, colon, and prostatic cancers, for example, and an increased consumption of cruciferous vegetables such as cabbage, broccoli, Brussels sprouts, and turnips has been associated with decreased cancer frequencies for colon, rectum, and bladder. Experimental studies, also, in several animal models have demonstrated in direct feeding studies that certain foods or crude food components provide significant protection against chemically induced or radiation induced tumorigenesis. Examples include the cruciferous vegetables (cabbage, cauliflower, broccoli, Brussels sprouts), celery, orange oil, beverage sources such as coffee and cocoa beans, and edible legumes such as soybeans or soybean concentrates. Diverse types of chemical compounds present in these foods have also been shown to inhibit the neoplastic process, including phenols, coumarins, isothiocyanates, flavonoids, and indoles. Topically applied onion and garlic oils, too, appear to act as anti-promoting agents in two-stage mouse skin tumorigenesis. Further, in in vitro studies a large number of fruits and vegetables have been shown to contain antimutagenic or "desmutagenic" factors with activity against several mutagens and carcinogens. Finally, some naturally occurring plant phenols have been shown to inhibit the mutagenicity and cytotoxicity of the only known ultimate carcinogenic metabolite of the polycyclic aromatic hydrocarbon, benzo(a)pyrene, in bacterial and mammalian cell assays; and naturally occurring tetrapyrroles, both porphyrins and open chain types, have also been shown to inhibit mutagenesis induced by certain classes of carcinogens. All of these laboratory and epidemiologic results suggest the possible importance to human cancer prevention of naturally occurring inhibitors of carcinogenesis, particularly those occurring as constituents of the human diet. The purpose of this RFA is to encourage additional research on these substances since their extent of occurrence, their role and potential as cancer preventive agents, and how their protective effects might be enhanced are little known at the present time.

II. OBJECTIVES AND SCOPE

Research conducted under this RFA will seek to expand knowledge and understanding of naturally occurring inhibitors of carcinogenesis and their potential for human cancer prevention. However, it is not the intent of this RFA to stimulate studies on retinoids (including natural vitamin A), vitamins C and E, or selenium; applications dealing with these agents will be considered non-responsive. Areas for emphasis (A, B, C, D) are shown below. All applications must respond to area A and at least one of the other areas (B, C, D) to be considered responsive to this RFA.

A. Identification of new naturally occurring inhibitors with special attention to appropriate methods of isolation of specific constituents or chemical forms. It is expected that foods consumed by man will constitute a primary source for these efforts. In this regard, the selected methods of isolation of specific constituents or chemicals from natural products or food materials should be the same as, or similar to, that of the natural food intake of man. That is to say, drastic methods of isolation should be avoided wherever possible, and where employed, should be specifically and carefully designed for the specific step(s) necessary. Isolation, purification, and identification procedures which are developed for these inhibitors should represent quantitative, reproducible, analytical methodologies which will permit analyses for their precise content in foods, so that a data-base can be established for such food-derived anticarcinogenic substances.

B. Thorough studies on mechanisms of action of newly identified inhibitors and their pharmacokinetics. Studies on mechanisms of action are a most important part of the proposed efforts which are regarded not simply as a wide range screening of foods or other natural products for inhibitors of carcinogenesis, but as integrated studies which will not only use the most advanced knowledge, techniques, and instrumentation of modern natural product chemistry for isolation, purification, and identification of inhibitors, but will also seek to determine the biochemical and biological bases for the inhibitions which are found. Very little is known about the absorption, distribution, metabolism, and excretion of natural inhibitors of carcinogenesis; studies on their pharmacokinetics will importantly complement studies on their mechanisms of action.

C. Improvement in current systems and development of new systems for identifying and studying naturally occurring inhibitors. A critical need exists for improvement of present models, and for development of new models, for identifying new naturally occurring inhibitors of carcinogenesis. This need exists for both in vitro and in vivo systems, and for both short-term reliable assay systems and systems for long-term studies. Development of shorter term assays for anti-promotion agents or anticarcinogenic agents active during the post-initiation phases of the neoplastic process is particularly needed.

D. Determination of the range of conditions under which efficacy of natural inhibitors is demonstrable. These investigations should include dose-response studies, species in which inhibition can be demonstrated, the range of carcinogens or spontaneous tumors against which activity exists, the anti-promoting activity of the natural inhibitor or its activity during the post-initiation period, the anti-initiation capacity of the agent, the precise time relationships between administration of inhibitor and carcinogen necessary for inhibition of tumorigenesis, and potential additive, synergistic or potentiating properties which the inhibitor may have in conjunction with other naturally occurring constituents of the diet.

Applications will also be accepted in which research is proposed on new synthetic inhibitors of carcinogenesis. However, such studies must fall into the areas of research given above, and substantial justification for performing the studies must be given. Such justification must be equivalent to that indicated in the Background section of this RFA (Section I). Analogues of known natural inhibitors of carcinogenesis synthesized as part of structure-activity investigations are one example of synthetic compounds acceptable for study. Such studies can be considered further attempts at defining mechanisms of action and pharmacokinetic properties with the aim of optimizing efficacy, decreasing toxicity, and altering distribution, disposition, and bioavailability.

III. MECHANISM OF SUPPORT

This RFA will use the traditional National Institutes of Health grant-in-aid. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed four years. The intent is to fund multiple projects, with total costs amounting to approximately $1.0 million for the first year. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the National Cancer Institute, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Each application submitted in response to the RFA will be reviewed by (1) an appropriate review panel of the Division of Research Grants, National Institutes of Health, and (2) the National Cancer Advisory Board. All applications will be evaluated on a competitive basis.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals and fall within one or more of the specified research categories (see II. OBJECTIVES AND SCOPE). If the application is judged by the National Cancer Institute not to be responsive, the applicant will have the opportunity of having the application considered along with other unsolicited applications received by the National Institutes of Health in the review cycle which is current at that time

The factors considered by the initial review group in evaluating each response to the RFA will be:

1. Scientific merit of research approach, design, and methodology.

2. Scientific, technical, or medical significance and originality of the proposed research.

3. Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.

4. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.

5. Adequacy of existing/proposed facilities, equipment, instrumentation, and other resources. Applications which specify a proposed use of human cells/tissues/fluids/excreta, need to provide assurance and details concerning the nature, source, and availability of those specimens.

6. Adequacy of practices, procedures, and facilities relative to the safe handling and use of chemical, biological and/or physical carcinogens.

7. Reasonableness of the proposed budget and duration.

V. METHOD OF APPLYING

A. Format of Application

Applications must be submitted on form PHS-398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the Division of Research Grants, NIH. The conventional presentation in format and detail applicable to regular research grant applications should be followed, and the requirements specified under Review Criteria (IV. B.) must be fulfilled. The words "**RFA-NIH-NCI-DCCP-CPCB-83-13, NATURAL AND SYNTHETIC INHIBITORS OF CARCINOGENESIS**" should be typed in section 2 on the face page of the grant application form.

B. Application Procedures

The completed original application and six (6) copies should be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

To ensure their review, applications should be received by November 15, 1983.

If applications are received after that date, the applicants will have the opportunity of having them considered in the next regular review cycle as unsolicited grant applications. Also, the Division of Research Grants (DRG) will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VI. INQUIRIES

Inquiries may be directed to:

Dr. Carl E. Smith
Chemical and Physical Carcinogenesis Branch
Division of Cancer Cause and Prevention
National Cancer Institute
Landow Building - Room 8C37
Bethesda, Maryland 20205

Telephone: (301) 496-4141

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DCT-CTEP-83-11

EXPLORATORY GRANT (P20) TO SUPPORT THE PLANNING AND DEVELOPMENT OF RESEARCH PROGRAMS IN SURGICAL ONCOLOGY

NATIONAL CANCER INSTITUTE

Application Receipt Date: November 15, 1983

The National Cancer Institute's (NCI) Division of Cancer Treatment (DCT) desires to expand support of surgical oncology research. This announcement solicits applications for exploratory grants (P20s), to support the planning and development of a research program in surgical oncology and contains specific instructions for P20 applications. A separate program announcement invites applications for individual research project (R01) and program project (P01) grants on an ongoing basis.

Grants are awarded to nonprofit and profit organizations and institutions, governments and their agencies, and occationally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary National Institutes of Health (NIH) grant-in-aid, in accordance with PHS policies applicable to research project grants including cost-sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to the RFA will be reviewed by the same NIH initial review group.

The present RFA announcement is for a single competition with a specified deadline of November 15, 1983, for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards will be made under the authority of the Public Health Service Act, Title IV, Part a (Public Law 78-410, as amended; 42 USC 282) and administered under PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

I. BACKGROUND INFORMATION
II. OBJECTIVES AND SCOPE
III. MECHANISM OF SUPPORT
IV. REVIEW PROCEDURES AND CRITERIA
V. METHOD OF APPLYING
VI. INQUIRIES
VII. NEGOTIATION AND AWARD
VIII. REPORTING REQUIREMENTS

I. BACKGROUND INFORMATION

The treatment of cancer has evolved as a multidisciplinary effort involving (but not limited to) the disciplines of medical, pediatric, surgical and radiation oncology. The disciplines of medical, pediatric and radiation oncology have developed strong programs in clinical investigations but academic development in surgical oncology has not kept pace. For most cancers surgery is the keystone of primary treatment, which is the setting for advamces in multidisciplinary therapy. Such advances are an important long-range objective of the DCT. The attainment of this goal requires substantial strengthening of academic programs in surgical oncology.

II. OBJECTIVES AND SCOPE

The purpose of this grant is to support the planning and development of a research program in surgical oncology. Examples of proposals that NCI considers for support include (but are not limited to):

- Planning the development of a research program in surgical oncology within the context of available staff and resources.

- Coordination of an institution's staff and resources for the purpose of preparing and submitting a large and complex grant application in surgical oncology (for example, preparation of a program project (P01) grant application).

- Assessment of an institution's needs in both personnel and material resources for the creation of an effective research program in surgical oncology. This might include feasibility studies in which the applicant would determine the potential for developing such a program and the validity of various approaches for implementing it.

The proposal should contain information on the following points:

A. Specific objectives of the planning effort for surgical oncology research programs at the principal investigator's institution.

B. Organization of the staff, facilities, and relevant existing programs in oncology and related disciplines at the institution.

C. Evidence of institutional commitment to a surgical oncology research program.

D. Specific information about what will be included in the planning effort. Activities whose major goals are training and research are not to be included.

E. Interaction of surgical oncology activities with other units or disciplines within the institution.

It is important to note that the award of an exploratory grant does not imply a commitment by NCI to future funding of any program planned and developed with the support of such a grant. Separate applications must be submitted for such projects which are then reviewed on the basis of merit.

III. MECHANISM OF SUPPORT

This RFA will use the NIH grant-in-aid. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals (see II. OBJECTIVES AND SCOPE). If the application is judged by the NCI not to be responsive, the applicant will have the opportunity of having the application considered along with other unsolicited applications received by the NIH.

The total project period for applications submitted in response to the present RFA should not exceed three years. Although there is no specific limitation on the amount of a grant request, NCI program staff intends to make approximately five to ten awards with total costs amounting to approximately $500,000 the first year. This funding level is dependent on the receipt of a sufficient number of meritorious applications. The number of grants funded may be increased depending on the availability of resources.

Also, although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the availability of funds for this purpose.

Allowable direct costs may include:

1. Salaries.

2. Supplies and pilot activities relative to the planning effort.

3. Payament of consultation and technical assistance needed for feasibility surveys and identification of special problems and alternatives. Consultant fees should not be paid to an employee of the United States Government. The applicant must include the following information when applying for consultant services in an Exploratory Grant.

    a. Evidence that the services to be provided are essential and cannot be provided by persons receiving salary support or otherwise compensated for their services under the grant.
    b. Evidence that a selection process has been or will be employed to secure the most qualified consultant available, considering the nature and extent of services required.

    c. Evidence that the proposed charges are appropriate, considering the qualifications of the consultant and normal charges for this type of service.

It should be emphasized that the applicant must not enter into a binding agreement with a consultant for expenditure of these grant funds prior to an award.

4. Other related costs.

Costs of alteration and renovation are not allowed.

Expenditures under these grants are subject to policies applicable to research project grants supported by the NIH as described in the current PHS Grant Policy Statement.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

All grant applications submitted to NIH are received by the Division of Research Grants (DRG). "The Planning and Development of Research Programs in Surgical Oncology" grant applications will be referred to an NCI review committee for initial scientific and technical review. Recommendations of all review committees are presented to the National Cancer Advisory Board (NCAB) for final review and recommendation to the NCI.

B. Review Criteria

The factors considered in evaluating each response to this RFA will be:

1. Objectives:
    - Feasibility of the objectives.
    - Clarity and appropriateness of the grant application.
    - Relevance of the proposal to the goals of the National Cancer Program.
2. Planning:
    - Composition and competence of the planning group.
    - Appropriate utilization of available staff and resources.
3. Applicant's commitment to cancer programs:
    - Background of applicant organization's commitment to cancer programs with reference to program content, personnel, facilities, and financial obligations and commitments.
    - Current priority of the cancer program with reference to such organizational or managerial requirements as those relating to delegation of authority, role of the cancer program within the organization, and commitment of personnel, facilities, and funds.

- Current organization of interdisciplinary cancer programs.

4. Project Director:

   - Background, training, and experience.

   - Leadership, scientific and administrative capabilities, and potential for development.

5. Scientific and other technical considerations:

   - Review and evaluation of the proposed planning effort.

   - Listing of professional staff in surgical oncology unit or in departments collaborating with surgical oncology.

   - Background and experience of the professional staff.

6. Administrative and organizational considerations:

   - Relationship of surgical oncology as an academic section or division to the department of surgery and other clinical and preclinical departments.

   - Letters of agreement from applicant organization, affiliated and other related or associated institutions.

   - Management capabilities pertaining to:

     Fiscal administration
     Procurement
     Property management
     Personnel management
     Facilities management
     Planning and budgeting
     Inventions and patents

7. Intellectual environment of applicant organization:

   - Description of existing academic programs in surgical oncology.
   - Description of academic programs in oncology and other biomedical disciplines other than surgical oncology.

   - Appropriate relationship of cancer program to applicant organization or parent institution.

   - Effect of cancer program on other programs of the institution or organization.

V. METHOD OF APPLYING

A. Format of Applications

Applications must be submitted on form PHS 398 (Rev. 5/82), the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the DRG, NIH. The title **"RFA, NIH-NCI-DTC,CTEP-83-11 - The Planning and Development of Research Programs in Surgical Oncology"** should be typed in section 2 of the first page of the application.

B. Application Procedure

The completed original application and four copies of the application must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

To ensure their review, applications must be received by November 15, 1983. Applications received after that date will be returned. Also, the DRG will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

Two copies of the application should be sent to:

Referral Officer
Grants Administration Branch
Division of Extramural Activities
National Cancer Institute
2115 East Jefferson Street, Room 401
Rockville, Maryland 20852

A copy of the covering letter should also be sent to Dr. deMoss at the address shown below.

VI. INQUIRIES MAY BE DIRECTED TO:

Ernest V. deMoss, M.D., M.P.H.
Head, Surgery Section
Clinical Investigations Branch
Division of Cancer Treatment
National Cancer Institute
National Institutes of Health
Landow Building - Room 4B04
Bethesda, Maryland 20205

Telephone: (301)496-4844

VII. NEGOTIATION AND AWARD

Applications recommended for approval by the NCAB and selected for funding will be negotiated by the NCI staff with the applicant institution. There will be a limit of one award per institution. A Notice of Grant Award will summarize the results of the negotiations.

VIII. REPORTING REQUIREMENTS

As with research grants, interim and terminal progress reports must be submitted to the NCI in accordance with the current PHS Grants Policy Statement. Terminal progress reports must be submitted within 90 days after the end of the project. The report should include the following information:

1. Summary statement or critique of progress toward achieving originally stated aims.
2. Description or listing of results, positive or negative, considered significant by the investigator.
3. List of publications emanating from the exploratory grant.
4. Presentation and evaluation of consultants' reports in cases where outside consultants have been used in planning the program. Copies of the consultants' written report shall also be included in the appendix of the terminal report.

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DRCCA-OD-83-7

LONGITUDINAL EVALUATION OF SCHOOL-BASED SMOKING PREVENTION PROGRAMS

NATIONAL CANCER INSTITUTE

Application Receipt Date: December 1, 1983

Letter of Intent Receipt Date: October 15, 1983

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute, (NCI) is interested in supporting studies which a) develop and evaluate school-based interventions to prevent the onset of habitual cigarette smoking, and provide for the long-term follow-up of the study cohorts and their controls; or, b) provide for the long-term follow-up of study cohorts and their controls who have been a part of previous, school-based programs that have been recognized as state-of-the-art interventions in smoking prevention.

The proposed studies should aid in determining the long-term effect that school-based smoking prevention programs have on the rates of adoption of habitual cigarette smoking among adolescents.

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary National Institutes of Health (NIH) grant-in-aid, in accordance with PHS policies applicable to Research Project Grants, including cost sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group.

The present RFA announcement is for a single competition with a specified deadline of December 1, 1983 for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301 (c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

I. BACKGROUND

Recent Surgeon General's Reports have identified cigarette smoking as the single most important environmental factor contributing to premature cigarette smoking is the major single cause of cancer mortality in the United States, contributing an estimated 30 percent to all cancer deaths. The most desirable approach to reducing tobacco-related cancer is to delay, reduce, or prevent the onset of habitual smoking behavior. Since the adolescent years are those in which the greatest risk for adoption of the smoking habit exists, it is also during these years, and those immediately preceding it, that the greatest opportunity for delay, reduction, or prevention of onset exists. Efforts to intervene in the smoking behavior of adolescents may be best served through school-based programs because more youth may be reached through this institution than any other and because schools provide an excellent structure for careful measurement of the effects of such programs.

Recent studies have demonstrated at least short-term reductions in cigarette use as a result of school-based interventions. Based on sound theoretical grounds, these studies have employed a wide array of approaches (e.g., teacher vs. peer-led programs, films and videotapes, life and social skills training, broad health promotion activities, family involvement) and methodologies (e.g., thiocyanate measurement for self-report validation, analysis of distinct levels of smoking, true random designs with schools as units of analysis). Nevertheless, the published research, as well as research in progress, leave remaining a number of important gaps in the knowledge base necessary to implement effective interventions. Additionally, it is essential to verify the long-term impact of such school-based interventions before resources are devoted to the significant problem of assuring that such interventions are disseminated to and used by school systems throughout the nation.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing school-based smoking intervention programs (or following up already existing ones) and determining the long-term effectiveness of these programs on the delay, reduction, or prevention of habitual cigarette smoking among adolescents.

The focus of the studies of interest must be on longitudinal intervention trials of school-based programs. It is anticipated, in keeping with the goals of the National Cancer Institute Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a large, distinct and well-characterized population or a sizeable sample of the population in such a way that the results obtained are representative of results in large target populations) investigations. Where justified and necessary, however, highly controlled substudies which focus on basic processes involved in cigarette use may be embedded in the intervention studies. These research questions should not, however, become the overriding interest of the study, but, rather, be integrated as complementary adjuncts to the interventions.

The studies sought are of two broad types:

A. New studies of promising school-based prevention programs (focused on youth at any point or set of points from kindergarten through 12th grade) which incorporate longitudinal follow-up (preferably into young adulthood, up to age 24); and

B. Longitudinal follow-up of existing cohorts of youth who have been part of a well-designed existing intervention program but have been subjected only to short-term evaluation, and whose size and composition justify generalizable conclusions.

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable and affordable by those schools desiring to do so.

It is recognized that experimentation in school settings with long-term follow-up is a difficult and complex task. Considering this and the current state of the art in school-based prevention programs, as well as the aims of this RFA, studies should consider and address where appropriate, the following research questions and issues (as well as numerous others not listed):

o Can school-based intervention programs produce long-term reductions in smoking onset? And, is the population and/or technique chosen for this study sufficiently stable to permit such long-term follow-up?

o Is the research design and data analysis plan rigorous enough to provide valid, reliable data yet flexible enough to accomodate field setting conditions?

o Are there a sufficient number of classrooms/schools to insure that any observed effects are not classroom/school specific?

o Is there sufficient justification (i.e. validity, reliability data) for the selection of program materials to be utilized or developed?

o Is the process evaluation design able to monitor the implementaion of key program components, identify which are most responsible for any program impact, and determine which are best/least well-received by the program participants?

o What type of self-report validation techniques are appropriate for the interventions planned? If none, what arguments support this position?

o Is it possible to identify and design appropriate interventions for youth who are at particularly high-risk for habitual cigarette smoking?

o What specific techniques are needed for interventions and follow-up studies of youth who are non-middle-class, minority, highly mobile or school dropouts? How will sociocultural differences in the study population affect the study design?

- Is there a role for the family (e.g., parents, siblings) or other support groups in school-based smoking intervention programs? If so, how could these groups be integrated into such efforts?

- How do environmental factors (e.g., school climate, community attitudes) interact with program components and affect the impact of the interventions?

- Will these interventions be more effective if they are designed as specific smoking education approaches or embedded within broader health education/behavior approaches? Which type of approach are schools more likely to utilize after the research has been completed?

- How useful are booster sessions in achieving long-term effects? How often are they needed? What should their focus be?

- What consideration must be given to the multiple domains of adolescent health and social behavior (e.g., psychological health, problem behaviors other than cigarette smoking, personal adjustment factors) in the design, content, and material development of the interventions?

- Can effective school-based prevention programs be sufficiently standardized or packaged so that they can be maintained and implemented by school personnel in the absence of continuing external funding sources?

- What is the optimum curriculum time needed for an intervention to have a positive impact? What ages/grade levels are most appropriate for intervention?

III. MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) grant-in-aid. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant. Although the total project period for applications submitted in response to the present RFA should not exceed five years, it is anticipated that up to ten years of support may be necessary to carry through some longitudinal designs (e.g., following youth who participate in an intervention at age 12 through age 22). Renewal applications for such studies will be required at 3-5 year intervals after the initial period of support. The intent is to fund up to five projects, with total costs for all projects amounting to approximately $1.5 million for the first year. This level of activity is dependent on the receipt of a sufficient number of applications of scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Each application submitted in response to the RFA will be reviewed by: (1) an appropriate review panel of the NIH; and (2) the National Cancer Advisory Board at one of its scheduled quarterly meetings. All applications will be evaluated on a competitive basis.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals. The factors considered in evaluating each response to this RFA will be:

1. Scientific merit of the research approach, design, generalizability, follow-up concerns, and quality assurance of the research.
2. Scientific and technical significance and originality of the proposed research.
3. Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.
4. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.
5. Relevancy and appropriateness of the specific target population along with assurance as to their accessibility.
6. Identity of sources of data and procedures for their analysis and assurances as to their accessibility.
7. Adequacy of steps taken to optimize and fully evaluate the durability of the intervention effects.
8. Likelihood of the intervention to be readily adoptable and affordable by those schools desiring to do so.
9. Generalizability of the findings to large segments of the population.
10. A willingness to work cooperatively with other projects of a similar nature and with the NCI on the project.
11. Reasonableness of the proposed budget and duration of the research.

V. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to submit a one-page letter of intent which includes a very brief synopsis of proposed areas of research and identification of any other participating institutions. This letter of intent should be addressed to Dr. Thomas J. Glynn at the address located under VI. The Institute requests such contact to provide an indication of the number and the scope of applications to be received and for the purposes of identification of overlap and/or redundancy with currently funded research. The letter of intent is not binding; it will not enter into the review of any proposal subsequently submitted nor is it a mandatory requirement for the submission of the application. Telephone inquiries are welcomed at any time prior to application.

B. Format of Application

Applications must be submitted on Form PHS 398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the Division of Research Grants (DRG), NIH. The conventional presentation format and details applicable to regular research grant applications should be followed, and the requirements specified under Review Criteria (see section IV., B.) must be fulfilled. The words **"PROPOSAL IN RESPONSE TO RFA NIH-NCI-DRCCA-OD-83-7, "Longitudinal Evaluation of School Based Smoking Prevention Programs"** must be typed in bold letters in space number 2 on the face page of the application.

C. Application Procedures

The completed original application and six (6) copies should be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

To ensure their review, applications should be received by December 1, 1983. Applications received after that date will not be considered under this RFA, but the applicant will have the opportunity of having them considered in the next regular grant review cycle. Also, the DRG will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VI. INQUIRIES

Inquiries may be directed to:

Thomas J. Glynn, Ph.D.
Program Director for Smoking Research
Office of the Director, DRCCA
National Cancer Institute
National Institutes of Health
Blair Building - Room 101
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8735

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DRCCA-OD-83-8

THE USE OF SELF HELP STRATEGIES IN SMOKING PREVENTION AND CESSATION

NATIONAL CANCER INSTITUTE

Application Receipt Date: December 1, 1983

Letter of Intent Receipt Date: October 15, 1983

The Smoking, Tobacco, and Cancer Program, National Cancer Institute is interested in supporting studies directed at reducing the long-term incidence/prevalence of cigarette smoking through the use of self-help strategies.

The proposed studies should seek to (1) develop and evaluate individual and/or group self-help strategies to eliminate, prevent, or reduce cigarette smoking and/or (2) develop and evaluate assessment procedures for determining the long-term effectiveness of existing self-help strategies in eliminating, preventing, or reducing cigarette smoking.

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program.

Applicants funded under the RFA are supported through the customary NIH grant-in-aid, in accordance with PHS policies applicable to Research Project Grants, including cost sharing. However, the RFA solicitation represents a single competition, with a specified dead-line for receipt of applications. All applications received in response to this RFA will be reviewed by an appropriate National Institutes of Health (NIH) Initial Review Group.

The present RFA announcement is for a single competition with a specified deadline of December 1, 1983 for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

I. BACKGROUND

Recent Surgeon General's Reports have identified cigarette smoking as the single most important environmental factor contributing to premature mortality in the United States. Further, these reports conclude that cigarette smoking is the major single cause of cancer mortality in the United States, contributing an estimated 30 percent to all cancer deaths. The most desirable approach to reducing tobacco-related cancer is to eliminate, prevent, or reduce habitual cigarette smoking.

Since the first Surgeon General's Report on the health consequences of cigarette smoking was published in 1964, an estimated 30 million people have quit smoking. Subsequent reports have suggested that a significant majority of those who have stopped smoking have done so without the aid of organized smoking cessation programs and that, indeed, most current smokers prefer to quit with a procedure they may use on their own.

In response to this preference, a number of self-help smoking interventions have been developed over the past decade. These strategies have included, as examples, the use of pamphlets, manuals and books, audiotape cassettes, and mass media messages and presentations.

Unfortunately, most self-help interventions for smoking have not been systematically evaluated and those that have, have been evaluated for only a brief period of time. Additionally, existing studies have not identified, for example, which self-help strategies or programs are most effective, which types of self-help materials are most effective with smokers during different stages of change, (e.g., pre-quitting, decision making, quitting and maintenance), what generalizations may be drawn across self-help strategies, under what conditions smokers make use of available self-help materials, and what interactions may exist among self-directed change, changes in an individual's environment, and environmental factors that may facilitate or interfere with self-quitting.

Although some valuable data have been obtained regarding self-initiated smoking interventions (e.g., identification of factors related to successful and unsuccessful self-quitting), a substantial gap exists in how to apply this information across broad populations and achieve long-lasting results.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in studying the use of self-help strategies in the durable prevention, elimination, or reduction of cigarette smoking.

The focus of the studies envisioned thus must be on the long-term effectiveness of self-help strategies. It is anticipated, in keeping with the goals of the National Cancer Institute Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a large, distinct and well-characterized population or a sizeable sample of the population in such a way that the results obtained are representative of results in large target populations) investigations. Where justified and necessary, however, highly controlled studies of the acquisition process, personality factors or other related research questions which could influence the self-help process may be embedded in the intervention studies. These research questions should not, however, become the overriding interest of the study but, rather, be integrated as complementary adjuncts to the interventions.

The studies sought are of two broad types:

A. Development and long-term evaluation of the effectiveness of individual and/or group self-help strategies to eliminate, prevent, or reduce cigarette smoking; and

B. Development and long-term evaluation of assessment procedures for determining the effectiveness of existing, well-designed self-help strategies to eliminate, prevent, or reduce cigarette smoking.

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable and affordable by those desiring to do so.

Considering the current state of the art in self-help smoking interventions, as well as the aims of this RFA, studies of the broad types called for above should consider, and address where appropriate, the following research questions and issues (as well as numerous others not listed):

- Can self-help intervention programs produce long-term cessation, reduction, prevention of cigarette smoking? And, is the population and/or technique chosen for this study sufficiently stable to permit such long-term follow-up?

- Is the research design and data analysis plan rigorous enough to provide valid, reliable data yet flexible enough to accomodate field setting conditions?

- Are there a sufficient number of individuals or groups to insure, to the extent possible, that any observed effects are linked to the intervention?

- Is there sufficient justification (i.e. validity, reliability data) for the selection of intervention materials to be utilized or developed?

- Is the process evaluation design able to monitor the implementation of key intervention components, identify which are most responsible for any intervention impact, and determine which are best/least well-received by the intervention participants?

- What type of self-report validation techniques are appropriate for the interventions planned?

- Is it possible to identify and design appropriate self-help intervention for individuals who are at particularly high-risk for starting or continuing habitual cigarette smoking?

- Are specific self-help techniques needed for interventions with individuals who are non-middle-class, minority, highly mobile, or less educated? How will sociocultural differences in the study population affect the study design?

- Is there a role for the family or other support groups in self-help smoking intervention programs? If so, how could these groups be integrated into such efforts?

- How do environmental factors (e.g., peer smoking status, community attitudes) interact with program components and affect the impact of the interventions?

- Will these interventions be more effective if they are designed as specific smoking self-help approaches or embedded within broader health behavior self-help approaches? Which type of approach are individuals more likely to utilize after the research has been completed?

- How useful are booster sessions in achieving long-term effects? How often are they needed? What should their focus be?

- What consideration must be given to the multiple domains of individual health and social behavior (e.g., psychological health, problem behaviors other than cigarette smoking, personal adjustment factors) in the design, content, and material development of the interventions?

- Can effective self-help intervention programs be sufficiently standardized or packaged so that they can be successfully used by a broad range of individuals in the absence of continuing external involvement?

- What is the optimum time needed for a self-help intervention to have a positive impact? What type of individual and what level of smoking involvement are the most appropriate for intervention?

- How should a self-help intervention approach the issue of smoking relapse?

- Is it possible that there may be a reactance effect to self-monitoring in these interventions and, if so, how might this affect the research?

- Have the broad range of self-help intervention delivery methods (e.g., in-person, mail, computer, mass-media) been considered?

- Is it possible to determine why self-quitting seems to be the most effective method of smoking cessation and thus identify individuals who may be in a pre-quitting stage and most amenable for a successful self-help program?

III. MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health grant- in-aid. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years; nevertheless, it is NCI's intent to support quality studies to their completion. Where more than five years is required, and the case is made for such, the possibility for longer studies will exist through competing renewal grant applications. The intent is to fund up to five projects, with total costs for all projects amounting to approximately $1.4 million for the first year. This level of activity is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the National Cancer Institute, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Each application submitted in response to the RFA will be reviewed by: (1) an appropriate review panel of the National Institutes of Health, and (2) the National Cancer Advisory Board at one of its scheduled quarterly meetings. All applications will be evaluated on a competitive basis.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals. The factors considered in evaluating each response to this RFA will be:

1. Scientific merit of the research approach, design, and methodology.
2. Scientific and technical significance originality of the proposed research.
3. Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.
4. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.
5. Relevancy and appropriateness of the specific target population along with assurance as to their accessibility.
6. Identity of sources of data, intervention materials, etc., and procedures for their analysis and assurances as to their accessibility.
7. Adequacy of steps taken to optimize and fully evaluate the durability of the intervention effects.
8. Likelihood of the intervention to be readily adoptable and affordable by those desiring to do so.
9. Generalizability of the findings to large segments of the population.
10. Willingness to work cooperatively with other projects of a similar nature and with the NCI on the project.
11. Reasonableness of the proposed budget and duration of the research.

V. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to submit a one-page letter of intent which includes a very brief synopsis of proposed areas of research and identification of any other participating institutions. This letter should be sent to Dr. Thomas J. Glynn (see address in following section).

The Institute requests such letters only to provide an indication of the number and the scope of applications to be received. The letter of intent is not binding; it will not enter into the review of any proposal subsequently submitted nor is it a necessary requirement for application. Telephone inquiries are welcomed at any time prior to application.

B. Format of Application

Applications must be submitted on Form PHS 398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the Division of Research Grants, NIH. The conventional presentation format and details applicable to regular research grant applications should be followed, and the requirements specified under Review-Criteria (IV.B.) must be fulfilled. The words **"PROPOSAL IN RESPONSE TO RFA NIH-NCI-DRCCA-83, The Use of Self-Help Strategies in the Prevention and Cessation of Smoking"** must be typed in bold letters in space number 2 on the face page of the application.

C. Application Procedures

The completed original application and six (6) copies should be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

To ensure their review, applications should be received by December 1, 1983. Applications received after that date will not be considered under this RFA, but the applicant will have the opportunity of having them considered in the next regular grant review cycle. Also, the Division of Research Grants (DRG) will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VI. INQUIRIES

Inquiries may be directed to:

Thomas J. Glynn, Ph.D.
Program Director for Smoking Research
Office of the Director, DRCCA
National Cancer Institute
National Institutes of Health
Blair Building - Room 101
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8735

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DRCCA-OD-83-9

EVALUATION OF PHYSICIAN/DENTIST DELIVERED INTERVENTIONS FOR SMOKING PREVENTION AND CESSATION

NATIONAL CANCER INSTITUTE

Application Receipt Date: January 1, 1984

Letter of Intent Receipt Date: October 15, 1983

The Smoking, Tobacco, and Cancer Program (STCP). National Cancer Institute (NCI) is interested in supporting studies directed at reducing the long-term incidence/prevalence of cigarette smoking by enhancing the effectiveness of physicians and dentists in prevention and cessation counseling and support.

The proposed studies should seek to (1) identify/develop, implement, and evaluate brief structured interventions for physicians and dentists to assist their patients with smoking prevention or cessation; and/or (2) develop and evaluate mechanisms to encourage physician and dentist utilization of smoking prevention and cessation interventions; and/or (3) develop and evaluate mechanisms to encourage patients to request assistance with smoking cessation from their physician or dentist.

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary National Institutes of Health (NIH) grant-in-aid, in accordance with PHS policies applicable to Research Project Grants, including cost sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group.

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

The present RFA announcement is for a single competition with a specified deadline of January 1, 1984 for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

I. BACKGROUND

Recent Surgeon General's Reports have identified cigarette smoking as the single most important environmental factor contributing to premature mortality in the United States. Further, these reports conclude that cigarette smoking is the major single cause of cancer mortality in the United States, contributing an estimated 30 percent to all cancer deaths. The most desirable approach to reducing tobacco-related cancer is to eliminate, prevent, or reduce habitual cigarette smoking.

Physicians and dentists are in a unique position to influence patients to change their smoking habits. Not only do they enjoy prestige and credibility as sources of health-related information, but there is also evidence that these groups are receptive to playing an increasing role in discouraging smoking. Preliminary data on the role that physicians may play in smoking intervention are encouraging but, even as these initial findings foster enthusiasm for this intervention approach, they raise important questions about the nature, importance, and efficacy of provider influence. We know very little about such issues as the most effective methods physicians and dentists can use to motivate patients to consider cessation and to assist patients in actually quitting and maintaining nonsmoking, about what kinds of patients are most readily influenced by provider messages, and what is involved in encouraging patients to request assistance concerning smoking from their physician or dentist. It is to these and numerous other related issues that this RFA is addressed.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing (or implementing already existing) physician/dentist delivered smoking interventions and determining the long-term effectiveness of these programs on the durable prevention, reduction, and cessation of cigarette smoking among patient populations.

The focus of the studies envisioned thus must be on the long-term effectiveness of physician/dentist interventions. It is anticipated, in keeping with the goals of the National Cancer Institute Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a distinct and well-characterized population or a sizeable sample of the population in such a way that the results obtained are representative of results in the large target populations) investigations.

Where justified and necessary, however, highly controlled studies of the acquisition process, physician/dentist attitudes or other related research questions which could influence the effectiveness of provider messages may be embedded in the intervention studies. These research questions should not, however, become the overriding interest of the study but, rather, be integrated as complementary adjuncts to the interventions.

The objective is to increase the effectiveness of physicians/dentists in providing smoking prevention and cessation interventions to their patients. The primary focus is on the role of physicians and dentists in the smoking interventions, although other health professionals (e.g., nurses, dental hygienists, pharmacists) may be included. No restrictions are set on physician, dentist, or patient populations, nor on settings or organizations (e.g., HMO's, work sites, clinics, and general speciality practice) that may be studied. Applicants are encouraged to seek the cooperation of physician/dentist professional organizations in obtaining large numbers of these professionals for study participation.

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable by a broad range of physicians and dentists.

Considering the current state of the art in physician/dentist smoking interventions, as well as the aims of this RFA, studies of the broad types called for above should consider and address where appropriate, the following research questions and issues (as well as numerous others not listed, depending on factors specific to the proposed study's objectives):

- Can physician/dentist intervention programs produce long-term reductions in smoking behavior? And, is the population and/or technique chosen for this study sufficiently stable to permit such long-term follow-up?

- Is the research design and data analysis plan rigorous enough to provide valid, reliable data yet flexible enough to accomodate field setting conditions?

- Are there a sufficient number of individuals or groups to insure, to the extent possible, that any observed effects are linked to the intervention?

- Is there sufficient justification (i.e., validity, reliability data) for the selection of intervention materials to be utilized or developed?

- What consideration must be given to the multiple domains of individual health and social behavior (e.g., psychological health, problem behaviors other than cigarette smoking, personal adjustment factors) in the design, content, and material development of the interventions?

- Can effective intervention programs be sufficiently standardized or packaged so that they can be successfully used by a broad range of physicians/dentists in the absence of continuing external involvement?

- What is the optimum number of contacts needed for this intervention to have a positive impact? What type of individual and what level of smoking involvement is most appropriate for intervention?

- How should this type of intervention approach the issue of smoking relapse?

- Is the process evaluation design able to monitor the implementation of key intervention components, identify which are most responsible for any intervention impact, and determine participants?

- What type of self-report validation techniques are appropriate for the interventions planned?

- Is it possible to identify and design appropriate interventions for individuals who are at particularly high-risk for starting or continuing habitual cigarette smoking?

- Are specific techniques needed for interventions with individuals who are non-middle-class, minority, highly mobile, or less educated? Do the interventions consider sociocultural differences among the participants?

- Is there a role for the family (e.g., spouse, children) or other support groups in physician/dentist smoking intervention programs? If so, how could these groups be integrated into such efforts?

- How do environmental factors (e.g., physician/dentist smoking status, community attitudes) interact with program components and affect the impact of the interventions?

- Will these interventions be more effective if they are designed as specific smoking interventions or embedded within broader health behavior approaches? Which type of approach are physicians/dentists more likely to utilize after the research has been completed?

- How useful are booster sessions in achieving long-term effects? Can they be integrated into this type of program? How often are they needed? What should their focus be?

- How do physician/dentist smoking behavior, perceptions and attitudes affect their effectiveness as intervenors?

- How does the physician/dentist's views of their patients' ability to control their smoking affect their effectiveness as intervenors?

- How will physician/dentist compliance with the interventions be monitored?

- Will health professionals other than physicians/dentists be involved in the intervention? What will their roles be?

III. MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health grant-in-aid. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years; nevertheless, it is NCI's intent to support quality studies to their completion. Where more than five years is required, and the case is made for such, the possibility for longer studies will exist through competing renewal grant applications. The intent is to fund up to five projects, with total costs for all projects amounting to approximately $1.3 million for the first year. This level of activity is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the National Cancer Institute, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Each application submitted in response to the RFA will be reviewed by: (1) an appropriate review panel of the NIH; and (2) the National Cancer Advisory Board at one of its scheduled quarterly meetings. All applications will be evaluated on a competitive basis.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals. The factors considered in evaluating each response to this RFA will be:

1. Scientific merit of the research approach, design, and methodology.
2. Scientific and technical significance and originality of the proposed research.
3. Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.
4. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.
5. Relevancy and appropriateness of the specific target population along with assurance as to their accessibility.
6. Identity of sources of data, intervention materials, etc., and procedures for their analysis and assurance as to their accessibility.
7. Adequacy of steps taken to optimize and fully evaluate the durability of the intervention effect.
8. Likelihood of the intervention to be readily adoptable by a broad range of physicians and dentists.
9. Generalizability of the findings to large segments of the population.
10. Willingness to work cooperatively with other projects of a similar nature and with the NCI on the project
11. Reasonableness of the proposed budget and duration of the research.

V. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to submit a one-page letter of intent which includes a very brief synopsis of proposed areas of research and identification of any other participating institutions. This letter should be sent to Dr. Thomas J. Glynn (see address in following section).

The Institute requests such letters only to provide an indication of the number and the scope of applications to be received. The letter of intent is not binding; it will not enter into the review of any proposal subsequently submitted nor is it a necessary requirement for application. Telephone inquiries are welcome at any time prior to application.

B. Format of Applcation

Application must be submitted on Form PHS 398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the Division of Research Grants (DRG), NIH. The conventional presentation format and details applicable to regular research grant applications should be followed, and the requirements specified under Review Criteria (IV.B.) must be fulfilled. The words **"PROPOSAL IN RESPONSE TO RFA NIH-NCI-DRCCA-OD-83-9, Evaluation of Physician/Dentist Delivered Interventions for Smoking Prevention and Cessation"** should be typed in bold letters in space number 2 on the face page of the application.

C. Application Procedures

The completed original application and six (6) copies should be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

To ensure their review, applications should be received by January 1, 1984. Applications received after that date will not be considered under this RFA, but the applicant will have the opportunity of having them considered in the next regular grant review cycle. Also, the DRG will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VI. INQUIRIES

Inquiries may be directed to:

Thomas J. Glynn, Ph.D.
Program Director for Smoking Research
Office of the Director, DRCCA
National Cancer Insitute
National Institutes of Health
Blair Building - Room 101
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8735

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA NIH-NCI-DRCCA-OD-83-10

DEVELOPMENT AND EVALUATION OF SMOKING PREVENTION AND CESSATION INTERVENTIONS USING THE MASS MEDIA

NATIONAL CANCER INSTITUTE

Application Receipt Date: January 1, 1984

Letter of Intent Receipt Date: October 15, 1983

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute (NCI) is interested in supporting studies to determine the long-term effect of mass media interventions designed to prevent the onset and/or reduce the prevalence of cigarette smoking behavior.

The proposed studies should seek to (1) develop and evaluate innovative techniques that signifcantly increase the long-term effect of single or multiple mass media interventions for smoking prevention or cessation; and/or (2) develop and evaluate innovative techniques for the reinforcement and maintenance of positive prevention and cessation behaviors generated as a result of mass media interventions; and/or (3) provide for the long-term follow-up of study cohorts and their controls who have been a part of previous, mass media interventions directed at smoking prevention and cessation.

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary National Institutes of Health (NIH) grant-in-aid, in accordance with PHS policies applicable to Research Project Grants, including cost sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group.

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

The present RFA announcement is for a single competition with a specified deadline of January 1, 1984 for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

I. BACKGROUND

Recent Surgeon General's Reports have identified cigarette smoking as the single most important environmental factor contributing to premature mortality in the United States. Further, these reports conclude that cigarette smoking is the major single cause of cancer mortality in the United States, contributing an estimated 30 percent to all cancer deaths. The most desirable approach to reducing tobacco-related cancer is to durably prevent, eliminate, or reduce habitual cigarette smoking.

Among the many approaches to smoking prevention and cessation available, it is the mass media which have the potential to reach many thousands of smokers at one time, offer a convenient and relatively inexpensive means for obtaining assistance with quitting, can substantially reduce the burden of providing such assistance through the health care system, and contribute to developing a social climate that is more supportive of prevention and cessation behavior. Mass media campaigns directed at smoking behavior have been used with increasing frequency in recent years. However, few studies have been conducted to assess the effects of specific campaigns. Those that have been done most often reveal minor, short-term effects on behavior change, but even the majority of these studies have been criticized for various aspects of their study design. Beyond that, little is known about the long-term effects of these interventions, and such issues as the relative effectiveness of their various components, their cost-effectiveness, and their generalizability. It is to these and other related issues which this RFA is addressed.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing media-based smoking intervention programs (or following up already existing ones) and determining the long-term effectiveness of these programs on the prevention and cessation of habitual cigarette smoking among defined populations.

The focus of the studies envisioned thus must be on the long-term effectiveness of media-based interventions. It is anticipated, in keeping with the goals of the National Cancer Institute Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a large, distinct and well-characterized population or a sizeable sample of the population in such a way that the results obtained are representative of results inlarge target populations) investigations. Where justified and necessary, however, highly controlled studies of the acquisition process, personality factors or other related research questions which could influence the effectiveness of the media process may be embedded in the intervention studies. These research questions should not, however, become the overriding interest of the study but, rather, be integrated as complementary adjuncts to the interventions.

The studies sought are of .wo broad types:

A. New studies of promising media-based intervention programs (focused either on broad, defined populations or on specifically-targeted populations) which incorporate longtudinal follow-up (i.e., no less than 1 year following the conclusion of the intervention; wherever justified, longer periods of follow-up to measure durability of intervention effects are encouraged); and

B. Longitudinal follow-up of existing cohorts which have been part of a well-designed media-based intervention program but have been subjected only to short-term evaluation, and whose size and composition justify generalizable conclusions.

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable by others with only minor modifications and little or no external aid.

It is recognized that media-based experimentation with long-term follow-up is a difficult and complex task. Considering this and the current state of the art in media-based smoking interventions, as well as the aims of this RFA, studies of the broad types called for above should consider, and address where appropriate, the following research questions and issues (as well as numerous others not listed, depending on factors specific to the proposed study's objectives):

- o Can media-based intervention programs produce long-term effects on smoking behavior? And, is the population and/or technique chosen for this study sufficiently stable to permit such long-term follow-up?

- o Is the research design and data analysis plan rigorous enough to provide valid, reliable data yet flexible enough to accomodate field setting conditions?

- o Are there a sufficient number of individuals or groups to insure, to the extent possible, that any observed effects are linked to the intervention?

- o Is there sufficient justification (i.e., validity, reliability data) for the selection of intervention materials to be utilized or developed?

- o Is the process evaluation design able to monitor the implementation of key intervention components, identify which are most responsible for any intervention impact, and determine which are best/least well-received by the intervention participants?

- o What type of self-report validation techniques are appropriate for the interventions planned?

- Is it possible to identify and design appropriate interventions for individuals who are at particularly high-risk for starting or continuing habitual cigarette smoking?
- Are specific media approaches needed for interventions with individuals who are non-middle-class, minority, highly mobile, or less educated? How will sociocultural differences in the study population affect the study design?
- Is there a role for the family or other support groups in media-based smoking intervention programs?
- How do environmental factors (e.g., time of year, community attitudes) interact with program components and affect the impact of the interventions?
- Will these interventions be more effective if they are designed as specific smoking approaches or embedded within broader health behavior approaches? Which type of approach are those with media access more likely to utilize after the research has been completed?
- How useful are booster campaigns in achieving long-term effects in media-based interventions? Are they feasible? How often are they needed? What should their focus be?
- What consideration must be given to the multiple domains of individual health and social behavior (e.g., psychological health, problem behaviors other than cigarette smoking, personal adjustment factors) in the design, content, and material development of the interventions?
- Can effective media-based intervention programs be sufficiently standardized or packaged so that they can be afforded and successfully used by a broad range of groups in the absence of continuing external involvement?
- What role will message and copy testing play in the study design?
- Will these interventions be more effective if they are conducted through media approaches alone or in conjunction with other smoking prevention/cessation efforts?
- What is the most effective programming tool to use for attracting and sustaining participation of smokers who want to quit? Are, for example, nightly news segments better than half hour programs broadcast over several weeks? Given the advantages and disadvantages of each of these approaches, how can they be used to achieve more effective results? Are there other programming formats that may be effective?
- Which medium or combination of media (e.g., radio, television, newspapers) is most effective? How can cable television be utilized for this purpose?

- What are the most effective promotion and publicity strategies for reaching those less predisposed to quit smoking?

- How cost-effective is the use of mass media for conducting smoking cessation clinics? How can their cost-effectiveness be improved?

- What types of media and/or interpersonal interventions would be effective for fostering maintenance of nonsmoking behavior? Would PSAs, for example, be adequate maintenance messages?

- In what ways can the broadcast and print materials be utilized beyond their original use? For example, what are the effects of repeated broadcasts? How effective are these materials when used as "small media" by work sites, community groups, health care professionals?

- What are the most effective approaches for developing and distributing the printed materials that accompany the broadcast programming?

- Which program formats work best -- for example, use of an expert who instructs the audience in smoking cessation skills or use of a panel of smokers participating in a clinic? To what extent would an interactional component such as a live telephone call-in system enhance the effectiveness of the media intervention?

III. MECHANISM OF SUPPORT

This RFA will use the NIH grant-in-aid. Responsibility for the planning, direction and execution of the pro-posed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years; nevertheless, it is NCI's intent to support quality studies to their completion. Where more than five years is required, and the case is made for such, the possibility for longer studies will exist through competing renewal grant applications. The intent is to fund up to five projects, with total costs for all projects amounting to approximately $1.8 million for the first year. This level of activity is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Each application submitted in response to the RFA will be reviewed by: (1) an appropriate review panel of the NIH; and (2) the National Cancer Advisory Board at one of its scheduled quarterly meetings. All applications will be evaluated on a competitive basis.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals. The factors considered in evaluating each response to this RFA will be:

1. Scientific merit of the research approach, design, and methodology.

2. Scientific and technical significance and originality of the proposed research.

3. Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.

4. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.

5. Relevancy and appropriateness of the specific target population along with assurance as to their accessibility.

6. Identity of sources of data, intervention materials, etc., and procedures for their analysis and assurance as to their accessibility.

7. Adequacy of steps taken to optimize and fully evaluate the durability of the intervention effect.

8. Likelihood of the intervention to be readily adoptable by others.

9. Generalizability of the findings to large segments of the population.

10. Willingness to work cooperatively with other projects of a similar nature and with the NCI on the project

11. Reasonableness of the proposed budget and duration of the research.

V. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to submit a one-page letter of intent which includes a very brief synopsis of proposed areas of research and identification of any other participating institutions. This letter should be sent to Dr. Thomas J. Glynn (see address in following section).

The Institute requests such letters only to provide an indication of the number and the scope of applications to be received. The letter of intent is not binding; it will not enter into the review of any proposal subsequently submitted nor is it a necessary requirement for application. Telephone inquiries are welcomed at any time prior to application.

B. Format of Application

Applications must be submitted on Form PHS 398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the DRG, NIH. The conventional presentation format and details applicable to regular research grant applications should be followed, and the requirements specified under Reveiw Criteria (IV.B.) must be fulfilled. The words **"IN RESPONSE TO RFA NIH-NCI-DRCCA-83, Development and Evaluation of Smoking Prevention and Cessation Interventions Using the Mass Media"** should be typed in bold letters in space number 2 on the face page of the application.

C. Application Procedures

The completed original application and six (6) copies should be sentor delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

To ensure their review, applications should be received by January 1, 1984. Applications received after that date will not be considered under this RFA, but the applicant will have the opportunity of having them considered in the next regular grant review cycle. Also, the Division of Research Grants (DRG) will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VI. INQUIRIES

Inquiries may be directed to:

Thomas J. Glynn, Ph.D.
Program Director for Smoking Research
Office of the Director, DRCCA
National Cancer Institute
National Institutes of Health
Blair Building - Room 101
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8735

ANNOUNCEMENT

THE IMMUNE BASIS OF RENAL DISEASE

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Application Receipt Dates: November 1, March 1, July 1

I. PURPOSE

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) invites qualified investigators to submit research grant applications for the support of research directed to gaining a further understanding of the role of the immune system in human renal diseases. This need has not only been expressed by ad hoc Advisory Committee consultants to the Kidney Disease and Urology Program and experts knowledgeable in nephrology and immunology, but is based on progress in basic immunology in the past 5-10 years and upon concern about chronic renal failure to which the chronic glomerulonephritides contribute 1/3 to 2/3 of patients. It is hoped that this announcement will stimulate a sustained growth in the number of applications relating to immune mechanisms and renal diseases submitted to NIH in the future.

II. DISCIPLINE AND EXPERTISE

The interdisciplinary nature of such renal studies will require collaboration among experts in areas such as the major disciplines of immunology, (cellular immunology, immunogenetics, immunochemistry, immunopathology and immunopharmacology), nephrology, renal physiology and pathophysiology, biochemistry, pathology, molecular/cellular biology, genetics and epidemiology.

III. BACKGROUND

Glomerulonephritis (GN), a relatively infrequent medical problem, has a major impact on the quality of life and comprises an enormous loss of human potential when it progresses to chronic renal failure. Most frequently it affects children and young adults and in this country causes annual mortality of over 12,000, morbidity of at least 4 million days, work loss of 765,000 days, and an estimated loss of earning power of greater than $15 M. Glomerular diseases are the leading causes of loss of renal function and are responsible for more than half of the patients (35,000-40,000), who require End Stage Renal Disease (ESRD) management by dialysis and/or renal transplantation, at an estimated annual expenditure of at least $600 M (one-third of the ESRD/Medicaid costs in 1982).

Evidence accumulated in the last few decades implicates immunologic factors in a variety of renal diseases, particularily the glomerulonephritides and interstitial nephropathies. The majority of immunologically mediated glomerular diseases are associated with immune complexes in glomeruli in both primary (e.g., membranoproliferative GN) and systemic (e.g., lupus nephritis) diseases. The immunologic mechanisms thus far defined involve deposition of immune complexes from the circulation or their formation in situ. Less common are diseases in which antibodies are directed against native glomerular basement membrane (anti-GBM), as in Goodpasture's syndrome.

Though these two immunopathologic mechanisms constitute the major forms of GN, it appears that additional immunological mechanisms are involved. Thus, some forms of GN lack antigen and/or antibody deposits but have clinical and laboratory features suggesting immunological causes. Examples are minimal change GN and the nephritis of systemic vasculitis. Lymphoid cell infiltrates in renal tissue also suggest that direct cell mediated immune injury may be a component of many forms of nephritis, with or without associated antibody deposition. In addition, the fundamental observations of cell mediated immune responses which underlie the humoral antibody and/or immune complex disturbances of the more common nephropathies require further exploration.

Although there is a paucity of information regarding the etiologies and pathogenesis of most immunologic renal diseases, nevertheless, during the past decade there have been major advances in understanding the pathophysiology of chronic renal failure. Notable also are advances related to factors which affect the expression of immune mediated renal injury: 1) the elucidation of the potential role of anionic charges on the basement membrane upon glomerular permeability and localization of antigen and antibody, and 2) the reporting of a significant influence of renal hemodynamic factors in renal damage with the potential of modifying glomerular filtration rate (GFR) and renal blood flow (RBF) by manipulations of dietary intake.

IV. OBJECTIVES AND SCOPE

This solicitation is prompted by a recognized need for an expanded research effort to gain greater insights into the immunopathogenetic mechanisms that may cause renal injury and to define mechanisms for arresting, treating and/or preventing immunologic renal disease.

Research on the involvement of the immune system relating to the development of immune renal injury is encouraged in the following areas:

- investigation of host factors (genetic and immunologic) that predispose to the development of immune complex GN and other forms of antibody mediated injury;
- studies to define the role of cell-mediated immunity in the pathogenesis of glomerulonephritis, such as minimal change disease;
- development of animal models in which cell-mediated injury is demonstrable;
- studies to better define the role of lymphoid cells (i.e., T suppressor and helper cells, cytotoxic T cells, natural killer cells, etc.) which may directly produce renal injury or which by immunoregulatory imbalance may cause disordered humoral immune responses;
- development of new markers and new ways of assessing functional activity of cells within infiltrates;

- o studies of purported nonimmunologic mechanisms that may influence immunologically-initiated renal diseases;
- o basic laboratory or clinical studies which have relevance to immunologic basis of renal disease.

The above are examples only and should not be viewed as all inclusive.

V. MECHANISM OF SUPPORT

The mechanism of support for this program will be the grant-in-aid. The regulations (Code of Federal Regulations, Title 42, Part 52 and, as applicable to the state and local governments, Title 45, Part 74) and policies which govern the research grant programs of the National Institutes of Health (NIH) will prevail. This program is described in the Catalog of Federal Domestic Assistance No. 13.849, Kidney, Urologic, and Hematologic Diseases Research.

The award of grants pursuant to this Program Announcement is contingent upon receipt of appropriated funds for this purpose. Although this solicitation is included in the NIADDK funding plan for Fiscal Year 1984, support is contingent upon receipt of funds for this purpose. The specific amount to be funded will depend upon the merit of the applications. It is expected that funding will begin July 1984.

VI. REVIEW PROCEDURES AND CRITERIA

A. Assignment of Applications

Applications will be received by the NIH, Division of Research Grants (DRG), referred to an appropriate Study Section for scientific merit review, and assigned to NIADDK for possible funding, unless programmatic considerations indicate more appropriate assignment to another Institute. These decisions will be governed by normal DRG Referral Guidelines.

B. Review Procedures

Applications in response to this solicitation will be reviewed on a nationwide basis in competition with other research grant applications, and in accord with the usual NIH peer review procedures. Applications will first be reviewed for scientific and technical merit by a review group composed mostly of non-federal scientific consultants (Study Section), and then by the National Advisory Coluncil of the NIADDK or other appropriate Institute. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

VII. METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions. The phrase **"PREPARED IN RESPONSE TO NIADDK KIDNEY PROGRAM ANNOUNCEMENT - THE IMMUNE BASIS OF RENAL DISEASE"** should be typed across the top of the first page of the applications.

The original and six copies of the application should be sent or delivered to:

Application Receipt
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

For further information, investigators are encouraged to contact the following individual:

M.J. Scherbenske, Ph.D.
Renal Physiology/Pathophysiology
Program Director
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
Westwood Building - Room 621
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7458

ANNOUNCEMENT

RESEARCH GRANTS IN THE FIELD OF NERVOUS SYSTEM MODULATION OF IMMUNE RESPONSES AND INTERACTIONS BETWEEN THE NERVOUS AND IMMUNE SYSTEMS

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application receipt dates: November 1, March 1, July 1

The Fundamental Neurosciences Program (FNP) of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the Immunology, Allergic and Immunologic Diseases Program (IAIDP) of the National Institute of Allergy and Infectious Diseases (NIAID) will welcome the submission of applications in the field of nervous system modulation of immune responses and interactions between the nervous and immune systems.

The central and peripheral nervous systems modulate the immune responses of any part of the body. The interactions, including feedback loops originating in either system, can occur via circulatory pathways (hormones and other chemical messengers) or via direct neural pathways, or via both.

A few examples of current research in this field are:

1. Effects of brain lesions upon antibody production, cellular immunocompetence, anaphylaxis, thymus and bone marrow functions, etc..
2. Changes in immune responses associated with classical or instrumental conditioning, or other psychological changes.
3. Changes in unit activity of neurons in the central nervous system during the course of immunogenesis.
4. Influences of environmental changes, mediated by neural or neurohormonal mechanisms, leading to alteration of immune competence.

These programs are described in the Catalog of Federal Domestic Assistance No. 13.854, Fundamental Neurosciences and No. 13.855, Immunology, Allergic and Immunologic Diseases. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended: 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

5. Anatomical, biochemical and physiological studies of receptor sites on cellular elements of the immune system for neurohormones, neurotransmitters, neuromodulators, and other neurally-active polypeptides.

6. Common embryological origins and parallel development of various tissues of the immune and nervous systems.

The FNP, NINCDS and the IAIDP, NIAID wish to encourage present investigations and to stimulate new research in this potentially highly significant but not widely appreciated area. Such research should lead to a better fundamental understanding of the mechanisms of interactions among the nervous, endocrine, and immune systems. This, in turn, should have enormous potential for the development of better preventive medicine and for improvement of current approaches to many clinical problems.

APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on form PHS 398 following instructions contained in the application kit. These forms are available in the business or grant offices of most academic and research institutions. If not, single application kits may be obtained from the Division of Research Grants (DRG), address below. The applications will be judged on scientific merit in accord with NIH policy and procedures involving peer review. Initial review will be by the appropriate study section of the DRG. Secondary review will be by the National Advisory Neurological and Communicative Disorders and Stroke Council and the National Advisory Allergy and Infectious Diseases Council. Primary assignments will be given to NINCDS for applications concerned with investigations primarily focused on neurophysiologic and neuropathologic mechanisms and interactions with elements of the immune system. Where the thrust of the proposed study is concerned with effects of immune system functions in health and disease on neural tissues, primary assignment will be given to NIAID. Applications judged more responsive to program interests of other Institutes will be assigned accordingly.

Application receipt dates are November 1, March 1 and July 1.

The phrase, **"NEURAL MODULATION OF IMMUNE RESPONSES"** should be typed in Section 2 on the front page of the grant application form. The original and six exact photocopies of the application should be mailed to the following address:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

For further information applicants may contact:

Dr. Novera Herbert Spector
FNP, NINCDS
National Institutes of Health
Federal Building - Room 916
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-5745

or

Dr. Bernard W. Janicki
Chief, Immunobiology and Immunochemistry Branch
IAIDP, NIAID
National Institutes of Health
Westwood Building - Room 757
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7551

ANNOUNCEMENT

RESEARCH ON THE PREVENTION OF ADM DISORDERS IN CHILDREN AND ADOLESCENTS

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

NATIONAL INSTITUTE ON DRUG ABUSE

NATIONAL INSTITUTE OF MENTAL HEALTH

Application Receipt Date: November 1, March 1

The Institutes of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) are interested in improving the scientific basis for the conceptualization, design, implementation, and evaluation of preventive interventions to reduce the incidence of alcohol abuse, drug abuse, and mental health (ADM) disorders in children and adolescents. Toward that goal, this announcement invites methodologically rigorous applications which use existing longitudinal data sets to improve understanding of: (1) interactions among known risk factors and precursors of ADM disorders; (2) temporal sequences whereby these risk factors and precursors evolve into ADM disorders; (3) models which clarify appropriate points for intervening in the development of ADM disorders; and (4) methodological and statistical procedures for conducting risk-factor and preventive intervention research.

Research strategies must use existing longitudinal data but may also incorporate the generation of additional data to supplement an existing longitudinal data set. Applications should reflect the concerns of the ADAMHA Institutes and examine the commonalities and distinctions in the development and prevention of ADM disorders in children and adolescents. Applications must address the interests of at least two of the three ADAMHA Institutes.

I. BACKGROUND

During the past decade, there has been increasing attention to the design, implementation, and evaluation of strategies to reduce the incidence of ADM disorders in the Nation's youth. Although advances have been made in the understanding of the methodological complexities of identifying risk factors which cut across ADM disorders and of the programmatic difficulties inherent in

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This program is described in the Catalog of Federal Domestic Assistance No. 13.242, Mental Health Research Grants, No. 13.273, Alcohol Research Programs, and 13.279, Drug Abuse Research Programs. Awards will be made under the authority of the Public Health Service Act Sections 301, 510 and 515, as amended and administered under PHS grant policies and Federal Regulations 42 CFR Part 52, Grants for Research Projects. This program is not subject to Health Systems Agency review.

preventive interventions aimed at multiple problems, to date, the development of demonstrably effective prevention strategies with such a focus has had only limited success.

Thus far, the majority of preventive intervention research efforts have been based on a conceptual model in which the precursors of ADM disorders are identified retrospectively. Rarely has the predictive validity of differences identified in this manner been substantiated, and even more rarely have the etiological and temporal processes involved in the evolution of the disorders been examined. Consequently, even when factors antecedent to a particular disorder have been accurately identified, preventive interventions may have failed because the intervention did not focus on those factors which mediated the development of underlying pathogenic processes.

II. RESEARCH CHARACTERISTICS

This announcement is intended to generate proposed research that will contribute to the development of preventive intervention models by examining prospectively the processes involved in the development of ADM disorders. A significant resource for that effort is the availability of longitudinal data sets which obtained initial assessments of individual, familial, cultural, and environmental variables on subject populations from infancy and early childhood on.

For purposes of this announcement, a longitudinal data set is expected to have the following minimal characteristics:

- The cohort(s) under investigation must be of adequate size and representativeness to allow for scientifically valid verification of known risk ractors and precursors of ADM disorders.

- The cohort(s) under investigation must have been assessed on two or more separate occasions with adequate overlap of measurement procedures at each point.

- If additional data are to be generated as part of the proposed research, the portion of the cohort(s) available for reassessment (or for which archival records are available) must be of adequate size and representativeness to allow for scientifically valid inferences.

Applicants are expected to discuss in detail the limitations of the data set to be used. Procedures for addressing limitations should be described. Investigators are encouraged to combine or compare existing data sets, if scientifically justified, in order to broaden the knowledge gained in the proposed research.

III. AREAS OF INVESTIGATION

Applications submitted under this announcement must address the concerns of more than one Institute and must be designed so that they apply directly to development or refinement of preventiveinterventions. Potential areas acceptable under this announcement include:

- Risk-factor research which uses existing longitudinal data sets alone or in combination with supplemental newly generated data on ADM status in order to assess the unique and interactive contribution of known risk factors and the precursors to the development of ADM disorders (e.g., family relationships, history of physical and/or psychological abuse, peer relationships, school adjustment problems, etc.).

- Research on the temporal aspects of ADM disorders which uses longitudinal data sets alone or in combination with supplemental newly generated data on ADM status in order to assess the temporal sequences whereby risk factors, precursors, and related mediating factors evolve into ADM disorders and which examines the optimal points in that sequence for introducing preventive interventions.

- Research on the factors related to the differential vulnerability/resistance to ADM disorders of individuals within known risk groups.

- Research which increases understanding of interactions among ADM disorders in the individual and examines the feasibility of applying findings from the above-mentioned research to the design of preventive interventions.

- Research on methodological/statistical obstacles to reanalysis of existing data sets, combining existing data with newly generated ADM assessments, archival records, and independently acquired data sets.

IV. APPLICATION CHARACTERISTICS

Applications submitted under this announcement must:

- Address problem areas of concern to more than one Institute.

- Focus on, or have potential for, early preventive interventions for ADM disorders, which are defined as actions which:

    - are implemented prior to or early in the development of the disorder or dysfunction and precede the need for treatment,

    - result in the demonstrable avoidance, abbreviation, or reversal of the disorder or dysfunction,

    - result in a demonstrable reduction of the incidence of the specific disorder or dysfunction.

- For risk-factor research proposals, present the following:

    - existing empirical evidence which clearly links the identified risk-factor with the disorder(s) to be prevented,

    - a research plan designed to elucidate how specific risk-factors evolve and interact as a basis for directly using this information to develop or refine a specific preventive intervention strategy.

- Reflect developmental and sociodemographic characteristics of the population being studied.

- Have access to longitudinal data sets and staff with appropriate methodological skills.
- Where indicated, reflect appropriate arrangements for collaboration with relevant prevention programs.

V. ELIGIBILITY

Grants are available to any nonprofit or profit-making institution, units of State or local government, and authorized units of the Federal Government.

VI. APPLICATION PROCEDURES

State and local government agencies should use form PHS-5161. All other applicants should use the standard PHS 398 (revised 5/82) research grant application form. **"Research on the Prevention of ADM Disorders in Children and Adolescents"** should be typed in item #2 on the face page of the application.

Application kits containing the necessary form and instructions may be obtained from most institutional business offices or offices of sponsored research for most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material:

Grants Operations Section
National Institute of Mental Health
Parklawn Building - Room 7C-05
5600 Fishers Lane
Rockville, Maryland 20857

The signed original and six (6) permanent legible copies of the complete application should be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

VII. CONSULTATION AND FURTHER INFORMATION

Potential applicants are encouraged to seek preapplication consultation.

Preapplication consultation and further information on program requirements of each of the individual Institues can be obtained from:

National Institute on Alcohol Abuse and Alcoholism

Ernestine Vanderveen, Ph.D.
Chief, Clinical and Psychosocial Research Branch
Division of Extramural Research
Room 14C-17

Telephone: (301) 443-4223

National Institute on Drug Abuse

Meyer Glantz, Ph.D.
Clinical Research Psychologist
Prevention Research Branch
Division of Clinical Research
Room 10A-16

Telephone: (301) 443-1263

National Institute of Mental Health

Morton Silverman, M.D.
Chief, Center for Prevention Research
Division of Prevention and Special
Mental Health Programs
Room 11C-06

Telephone: (301) 443-4283

The mailing address for the above is:

Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

VIII. REVIEW PROCESS

Applications received under this announcement will be assigned to a single Institute for review and administration if an award is made. Applications will be reviewed for scientific merit by a peer review group consisting primarily of non-Federal experts. Since these applications are expected to cut across several fields, special attention will be given to ensuring that appropriate expertise is available for their review.

Applications will receive a secondary review for scientific/technical merit and policy consideration by the National Advisory Councils of the ADAMHA Institutes. Notification of review outcome will be sent to the applicant by the Institute which is assigned primary responsibility for the particular application. Only applications recommended for approval by the relevant Councils can be considered for funding.

IX. APPLICATION RECEIPT AND REVIEW SCHEDULE

Receipt of Applications	Initial Review	Advisory Council Review	Earliest Award Date
November 1, 1983	Feb-Mar, 1984	May-June, 1984	July 1, 1984
March 1, 1984	May-June, 1984	Sept-Oct, 1984	December 1, 1984

X. REVIEW CRITERIA

Criteria for scientific/technical merit review of applications will include the following:

- Significance and originality from a scientific or technical standpoint of the goals of the proposed research.
- Adequacy of the methodology proposed to carry out the research.
- The qualifications and experience of the principal investigator and proposed staff.
- Reasonable availability of resources necessary for the research.
- Reasonableness of the proposed budget and duration in relation to the proposed research.
- The adequacy of provisions for the protection of human subjects.

In addition, the following special factors will be considered in assessment of specific types of applications:

Risk-factor research

- Linking the risk-factor(s) to be studied to specific ADM disorders.
- Soundness of theoretical rationale for proposed approach to elucidating how the risk-factor(s) evolve into, or relate to, specific ADM disorders.
- Scientific suitability of data set for proposed research.
- Potential for direct and useful application of findings to development or refinement of specific preventive intervention strategies

Methodological research

- Potential for direct and useful application to development or refinement of preventive intervention strategies or evaluation.

XI. AWARD CRITERIA

Applications recommended for approval will be considered for funding on the basis of:

- Scientific and technical merit as determined by the peer review process.
- Potential contribution to the areas identified in this announcement.
- Availability of funds.

XII. TERMS AND CONDITIONS OF SUPPORT

Grant funds may be used for expenses clearly related and necessary to carry out prevention research projects, including both direct costs which can be specifically identified with the project and allowable indirect costs of the institution. Research grant support is not provided to establish, add a component to, or operate a preventive intervention program. Support for research-related costs of prevention programs may be requested only for those particular costs and for that period of time required by the research. Such costs must be justified in terms of research objectives, methods, and design which promise to yield important generalizable knowledge and/or make a significant contribution to theoretical concepts. If such costs are requested, applicants must provide a description of other sources of support that have been explored for them. Because of limited research funds, there is a need to keep these types of costs to a minimum in research projects, and, even where justified, the full amount requested may not be awarded.

Grants will be administered in accordance with the PHS Grants Policy Statement including the policy regarding cost sharing. In addition, the applicant should be aware that portions of the following regulations may be relevant and applicable:

42 CFR 2	Confidentiality of Alcohol and Drug Abuse Patient Records
42 CFR 52	Grants for Research Projects
45 CFR 46	Protection of Human Subjects
45 CFR 74	Administration of Grants

XIII. AVAILABILITY OF FUNDS

Applications received under this announcement will be considered for funding in Fiscal Year 1984 and in Fiscal Year 1985. It is estimated that up to $500,000 will be available for new awards during this period.

XIV. PERIOD OF SUPPORT

Applications that propose to analyze data may request support for a period of up to 2 years. Applications that also propose to supplement data sets may request up to 3 years of support.

XV. ADDITIONAL SUPPORT FOR RESEARCH ON PREVENTION OF ADM DISORDERS IN CHILDREN AND ADOLESCENTS

This announcement is a specific initiative of the ADAMHA Institutes. The Institutes have ongoing programs to support a wide range of research on the prevention of ADM disorders in children and adolescents. The contact persons listed under Section VII - CONSULTATION AND FURTHER INFORMATION will provide information on those programs. Announcements of additional special initiatives may also be issued.

ANNOUNCEMENT

FAMILY THERAPY AND PREVENTION RESEARCH

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

NATIONAL INSTITUTE ON DRUG ABUSE

I. INTRODUCTION

The purpose of this announcement is to stimulate investigator interest in a research area of particular importance to the national drug abuse research program which is authorized under Sections 301 and 515 of the Public Health Service Act (42 U.S.C. 241). This program is described in the Catalog of Federal Domestic Assistance No. 13.279, Drug Abuse Research Programs.

The research program called for in this announcement is the study of the efficacy of family therapy in:

- The treatment of adolescent drug abusers, and
- The prevention of drug abusing behavior in the younger siblings of those adolescent drug abusers.

Through the Family Therapy and Prevention Research Program, the National Institute on Drug Abuse (NIDA) intends to encourage and stimulate research on brief, systems oriented family therapy* in the treatment of adolescent drug abusers and in the prevention of drug use among their younger siblings. The view of family therapy represented here differs considerably from the tradition way of looking at family members as having influence on the index patient. Quite simply, it is seen as an intervention affecting the entire family. Although modification of the index patient's symptom(s) is an important goal, a further goal is that family functioning improve. Thus, it is anticipated that growth and change through family therapy can result not only in decreased drug use among adolescent drug abusers, but also in clear-cut primary prevention of future family problems, including drug misuse and abuse among siblings.

II. BACKGROUND

Considerable attention has been focused on familial factors which are related to drug abuse. Both structural factors, such as broken homes, and interpersonal factors, such as the quality of parent-child relationships, have been addressed, and there is a growing conviction that the family plays a powerful role in the initiation, maintenance, cessation and prevention of the drug using behavior of its members. In this context, since the early 1970's, there has been growing interest in the application of family therapy to the treatment of drug abuse, especially among adolescents. The applicability of family therapy to drug abuse prevention has more recently received attention. If family therapy is effective, a family system is changed, supporting the healthy development of the children.

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* For purposes of this announcement brief, systems oriented family therapy is defined as therapy in which the family is seen as a group, and in which the treatment focus is on the interaction among family members and the functions of symptoms in the maintenance of the family system. Duration of treatment is generally limited to 16 weeks or less.

Although the number is increasing, there have been relatively few controlled outcome studies which support the utility of family therapy in the prevention and treatment of drug abuse and other behavioral problems. The purpose of this announcement is to encourage rigorous controlled studies, within the outline described below.

A. Application Characteristics

1. Experimental Treatment: The research solicited under this announcement is limited to those brief, systems oriented family therapies which are prevalent in the drug abuse treatment and prevention field (i.e., structural, strategic, communications, and behavioral family therapies), and in which the length of family treatment does not exceed approximately 16 weeks. It is desirable that both parents or parent surrogates (i.e., individuals fulfilling the parental role) be involved in treatment. Individuals who have only one parent or parent surrogate should also be included.

2. Subjects: The target population for this program consists of families with adolescent drug abusers, ages 13-19. The presenting drug abuser should have a history of use or abuse of illicit drugs for a period of at least three months preceding treatment entry. Individuals who have used marijuana only should have used at least an average of three times weekly over the prior three month period to qualify for study inclusion. While individuals may be included who have combined drug and alcohol abuse problems, history of use of alcohol alone is not considered to be drug abuse for purposes of this research program. Since this research program is interested in the efficacy of family therapy for prevention as well as the treatment of drug abuse, the study sample is further limited to families in which there are one or more siblings younger than the presenting abuser to permit analysis of prevention effects. Families included in the study should represent a cross-section of sociodemographic characteristics.

3. Research Design: Research supported under this announcement must be able to differentiate the effects of family therapy per se from the effects of increased attention to the family or any non-therapeutic emphasis on family functioning. Thus, it is anticipated that the research will minimally require at least two comparison treatments, treatment as usual exclusive of family therapy services (e.g., drug abuse counseling provided within drug abuse treatment programs) and a presumably low yield non-therapeutic family intervention (e.g., didactic multi-family discussion groups in which there are no therapeutic or counseling interventions). It is anticipated that subjects will be randomly assigned to the treatment conditions.

4. Specification of Treatments: It is essential that the proposed treatments are clearly defined and that the treatments are delivered in accord with the stated treatment protocols. Thus, an important aspect of this study is the development and use of manuals which specify the

treatment protocols for the experimental family therapy intervention and the comparison family intervention(s). It is expected that the manuals will be an essential part of a total package of staff training. Procedures should contain sufficient and appropriate details to ensure that the family therapy approach studied can be differentiated from other types of family therapy and from the comparison family intervention, and that the treatment protocols are being followed in the delivery of client treatment. While the framework of the manuals and training programs should be included in the grant application, it is anticipated that these will be finalized during the first few months of the grant. Manuals should be suitable not only for specifying the treatment during the research project, but also for publication following study conclusion.

5. Characteristics of Treatment Staff: It is essential that treatment staff be well qualified. Minimum requirements for family therapists include an advanced degree in the helping professions (i.e., psychiatry, psychology, psychiatric social work or psychiatric nursing) and a minimum of two years of experience with family therapy. Preference should be given to therapists with experience in working with drug abuse clients. For the comparison family intervention, counselors shall have an advanced degree and a minimum of two years experience in group counseling or group work and shall be knowledgeable about family dynamics. Again, preference should be given counselors with experience in working with drug abuse clients.

6. Measurement: Three categories of outcome measurements are suggested, one category oriented toward the primary presenting problem (the adolescent's drug abuse) and its corollaries, a second category oriented toward the family dynamics and problems, and a third category oriented toward the younger sibling to evaluate the treatment's preventive effects. In regard to the presenting abuser and younger siblings, it is important to include such variables as employment or school performance and involvement with the criminal justice system, in addition to standard drug and alcohol use measures. Data for both the individual and family categories should be collected from multiple sources, such as self-reports, third-party reports, and objective tests and observations. Follow-up data should be gathered for at least two years following completion of treatment, with assessments occurring immediately following treatment, six months, one year, and two years thereafter.

   Measures of individual dynamics such as the Psychiatric Status Schedule (Spitzer er al.) and the Behavior Problem Checklist (Quay and Peterson) and measures of family dynamics such as the Family Environment Scale (Moos), the Beavers-Timberlawn Family Evaluation Scale (Lewis et al.), and FACES II (Olson) are examples of appropriate instruments that may be considered for use in the study. Instruments must have established reliability and validity.

   In addition to outcome assessment, a comprehensive process evaluation is required. This assessment should carefully document the nature and extent of recruitment and treatment efforts.

7. Availability of Subjects: Applicants should carefully document the availability of sufficient subjects for the effective implementation of the research project. If recruitment will depend on referrals from other agencies, detailed letters of cooperation with the relevant agencies should be included as appendices to the application. Special recruitment strategies for low income and ethnic minority groups are encouraged in order to assure sufficient subjects to permit analyses of these groups.

8. Collaboration: To enchance the generalizability of findings, comparability of research procedures and instrumentation among various grantees under this program is desirable. Thus, applications from collaborating investigators are encouraged. To further facilitate exchange of information and collaboration where possible among funded projects, NIDA will sponsor meetings for investigators. Applicants may request funds for two trips to the Washington, D.C. area during the first year of the grant and one trip in each subsequent year for this purpose.

III. APPLICATION

Applications may be submitted by nonprofit, for-profit, or public organizations.

The regular research grant application form PHS 398 (Rev. 5/82) must be used in applying for these awards. However, State and local agencies should use form PHS 5161 (Rev. 3/79). Application kits are available in university grant offices or from the following:

Grants Management Branch
National Institute on Drug Abuse
Parklawn Building - Room 10-25
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-6710

The original and six copies of applications (original and 2 copies if PHS 5161 is used) must be submitted to:

Division of Research Grants
Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

IV. FURTHER INFORMATION AND CONSULTATION

Further information about the areas of interest described in this announcement may be obtained by contacting the following individual:

Dr. Robert J. Battjes
Chief, Prevention Research Branch
Division of Clinical Research
National Institute on Drug Abuse
Parklawn Building - Room 10A-16
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-1514

Investigators are encouraged to submit concept papers or outlines of their research to NIDA staff prior to preparing an application.

Investigators who wish to pursue other types of family therapy research than specified under this announcement, should contact:

Mr. George Beschner
Acting Chief, Treatment Research Branch
National Institute on Drug Abuse
Parklawn Building - Room 10A-30
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4060

V. REVIEW PROCEDURES

Review procedures for applications to this program conform to peer review procedures applicable to all research grants programs sponsored by the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). Applications are reviewed for scientific merit by an initial peer review group; the National Advisory Council on Drug Abuse performs a second review which may be based on policy as well as scientific merit considerations. After the Council provides final recommendations, applicants are notified of the results of the review.

VI. REVIEW CRITERIA

Criteria to be considered in evaluating applications include, but are not limited to:

- Evidence that the applicant has the potential to assemble an appropriate team of experienced service providers and to successfully utilize the family therapy modality in the treatment and prevention of drug abusing behavior.
- Qualifications and experience, specifically in treatment/prevention research of the investigative team; the challenges of this research call for the most experienced researchers.
- Originality and potential significance of the proposed research.
- Scientific soundness, appropriateness, and feasibility of the subject recruitment strategies, research design, outcome measures to be utilized, and data analysis plans for measuring treatment and prevention effects.
- Adequacy of plans for treatment manuals and staff training.
- Adequacy of the facilities, resources, and administrative structure for achieving the research objectives.
- Potential replicability of the proposed family therapy approach in drug abuse treatment and prevention programs.
- Adequacy of proposed budget and timeframes for the project.
- Adequacy of proposed procedures for the protection of human subjects.

VII. AWARD CRITERIA

Criteria for funding of applications include the scientific merit of the proposal, as determined by peer review, balance and compatability among proposed projects, and relevance to national need as reflected in NIDA's research priorities and plans. The availability of funds will also be considered in determining which awards will be made.

VIII. AVAILABILITY OF FUNDS

Up to $750,000 will be available to initiate research projects in response to this announcement during Fiscal Year 1984. It is anticipated that up to three projects will be funded. Funding for new projects in subsequent years will be dependent on available funds and program priorities.

IX. APPLICATION RECEIPT AND REVIEW SCHEDULE

Receipt Dates Renewal/New	Initial Review Committee	Council Meeting	Earliest Possible Start Date
Feb 1/Mar 1	June	Sept/Oct	December 1
Jun 1/Jul 1	October	Jan/Feb	April 1
Oct 1/Nov 1	February	May	July 1

X. PERIOD OF SUPPORT

Applications may request support for a period of up to five years. It is anticipated that five years of support will be needed to provide sufficient time to assess prevention effects on younger siblings as they mature, The treatment phase of the project should be completed within the first three years.

A competing continuation (i.e., a renewal) application may be submitted before the end of project period. A competing supplemental application may be submitted during an approved period of support to expand the scope or protocol during the project period.

ANNOUNCEMENT

RESEARCH AND DEMONSTRATIONS RELATING TO OCCUPATIONAL SAFETY AND HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Application Receipt Dates: November 1, March 1, and July 1

For All Except Small Grants Which Have Receipt Dates Of:

October 1, February 1, and June 1

The Centers for Disease Control (CDC), National Institute for Occupational Safety and Health (NIOSH) announces that competitive grant applications are being accepted for research and demonstrations relating to occupational safety and health. These include innovative methods, techniques, and approaches for dealing with occupational safety and health problems in the general industry and in the mining industry.

Support in the form of project grants will be awarded for annual budget periods, within a project period not to exceed five years.

I. AUTHORITY

These grants will be awarded and administered by NIOSH under the research and demonstration grant authority of Section 20(a) (1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669 (a)(1) and section 501 of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951). Program regulations applicable to these grants are contained in Part 87 of Title 42, Code of Federal Regulations, "National Institute for Occupational Safety and Health Research and Demonstration Grants." Except as otherwise indicated, the basic grant administration policies of the Department of Health and Human Services and the Public Health Service are applicable to this program.

II. ELIGIBLE APPLICANTS

Eligible applicants include non-profit and for-profit organizations. Thus universities, colleges, research institutions and other public and private organizations including State and local governments and small, minority and or woman-owned businesses are eligible for these research and demonstration grants. For-profit organizations will be required to submit a certification as to their status as part of their application.

III. PROGRAM REQUIREMENTS

A. Research Project Grants

A research project grant application should be intended and designed to establish, discover, develop, elucidate, or confirm information relating to occupational safety and health, including innovative methods, techniques, and approaches for dealing with occupational safety and health problems. These studies may generate information that is readily available to solve problems or contribute to a better understanding of underlying causes and mechanisms.

B. Demonstration Grants

A demonstration grant application should address, either on a pilot or full-scale basis, the technical or economic feasibility or application of: (1) a new or improved occupational safety or health procedure, method, technique, or system, or (2) an innovative method, technique, or approach for preventing occupational safety or health problems.

C. Small Grants

A small grant application is intended to provide financial support to carry out exploratory or pilot studies, to develop or test new techniques or methods, or to analyze data previously collected. This small grant program is intended for predoctoral graduate students, post-doctoral researchers (within three years following completion of doctoral degree or completion of residency or public health training) and junior faculty members (no higher than assistant professor). If university policy requires that a more senior person be listed as principal investigator the application should specify that the funds are for the use of a particular student or junior level person and should include appropriate justification for this arrangement. Though biographical sketches are required only for the person actually doing the work, the application should indicate who would be supervising the research. Small grant applications should be identified as such on the application form.

The total small grant award may comprise direct costs of up to $15,000 per year and additional indirect costs, as appropriate. The grants may be awarded for up to two years and are thereafter continuable by competitive renewal as a regular research grant. Salary of the principal investigator as well as that of the junior investigator, if university policy requires a senior person to be listed as the principal investigator, will not be allowed on a small grant, though salaries can be requested for necessary support staff such as laboratory technicians, interviewers, etc.

D. Program Project Grants

NIOSH will also accept applications for program project grants, but only after discussion with the individuals listed in this announcement.

IV. PROGRAMMATIC INTEREST

Examples of work-related programmatic interest to NIOSH which are applicable to all of the above types of grants are:

1. Occupational lung diseases: asbestosis, byssinosis, silicosis, coal workers' pneumoconiosis, lung cancer, occupational asthma*
2. Musculoskeletal injuries: disorders of the back, trunk, upper extremity, neck, lower extremity; traumatically induced Raynaud's phenomenon*
3. Occupational cancers (other than lung): leukemia; mesothelioma; cancers of the bladder, nose, and liver*
4. Amputations, fractures: eye loss, lacerations, and traumatic deaths*
5. Cardiovascular diseases: hypertension, coronary artery disease, acute myocardial infarction*
6. Disorders of reproduction: infertility, spontaneous abortion, teratogenesis*
7. Neurotoxic disorders: peripheral neuropathy, toxic encephalitis, psychoses, extreme personality changes (exposure-related)*
8. Noise-induced loss of hearing*
9. Dermatologic conditions: dermatoses, burns (scaldings), chemical burns, contusions (abrasions)*
10. Psychologic disorders: neuroses, personality disorders, alcoholism, drug dependency*
11. Control technology research: application of scientific principles to control strategies; preconstruction review; technology forcing/new source performance concepts; technology transfer; substitution; unit operations approaches*
12. Respirator research: new and innovative respiratory protective devices; techniques to predict performance; effectiveness of respirator programs; physiologic and ergonomic factors; medical surveillance strategies; psychological and motivational aspects; effectiveness of sorbents and filters, including chemical and physical properties*

*The conditions or examples listed under each category are to be viewed as selected examples, not comprehensive definitions of the category. It should be noted, however, that investigators may apply in any areas related to occupational safety and health. Applications responding to this announcement will be reviewed by staff for their responsiveness and relevance to occupational safety and health. Those considered non-responsive will be assigned in accordance with regular program guidelines. Potential applicants with questions concerning the acceptability of their proposed work should contact the individuals listed in this announcement.

V. CRITERIA FOR REVIEW

Applications will be evaluated by a dual review process. The primary (peer) review is based on scientific merit and significance of the project, competence of the proposed staff in relation to the type of research involved, feasibility of the project, likelihood of its producing meaningful results, appropriateness of the proposed project period, adequacy of the applicant's resources available for the project, and appropriateness of the budget request.

Demonstration grant applications will be reviewed additionally on the basis of the following criteria:

- Degree to which project objectives are clearly established, obtainable, and for which progress toward attainment can and will be measured.
- Availability, adequacy, and competence of personnel, facilities, and other resources needed to carry out the project.
- Degree to which the project can be expected to yield or demonstrate results that will be useful and desirable on a national or regional basis.
- Extent of cooperation expected from industry, unions, or other participants in the project, where applicable.

Small grant applications will be reviewed additionally on the basis of the following criteria:

- The review process will take into consideration the fact that the applicants do not have extensive experience with the grant process.

A secondary review will also be conducted. Factors considered in the secondary review will include:

- The results of the initial review.
- The significance of the proposed study to the research programs of NIOSH.
- National needs and program balance.
- Policy and budgetary considerations.

VI. APPLICATION AND AWARD

Applications should be submitted on Form PHS-398 (revised May 1982) or PHS-5161-1 for State and local government applicants. Forms should be available from the institutional business offices or from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 449
5333 Westbard Avenue
Bethesda, Maryland 20205

The original and six copies of the application must be submitted to the address below on or before the specified receipt dates in accordance with the instructions in the PHS-398 packet:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

In developing the application please note that the conventional presentation for grant applications should be used and the points identified under "CRITERIA FOR REVIEW" must be fulfilled.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application that are made available to outside reviewing groups. If the applicant organization elects to exercise this option, use asterisks on the original and six copies of the application to indicate those individuals for whom salaries and fringe benefits are being requested; the subtotals must still be shown. In addition, submit an additional copy of page four of Form PHS-398, completed in full with the asterisks replaced by the amount of the salary and fringe benefits requested for each individual listed. This budget page will be reserved for internal PHS staff use only.

The instructions in the Form PHS-398 packet should be followed concerning deadlines for either delivering or mailing the applications. The application should be sent or delivered using the mailing label in the Form PHS-398 packet.

The proposed timetable for receiving applications and awarding grants is as follows:

All Except Small Grants

Application Deadline	Primary Review Group Meeting	Secondary Review Meeting	Expected Start Date
March 1	June	September	December1
July 1	Oct./Nov.	January	April 1
November 1	Feb./Mar.	May	MayJuly 1

Small Grants

February 1	June	September	December 1
June 1	Oct./Nov.	January	April 1
October 1	Feb./Mar.	May	July 1

Awards will be made based on priority score ranking and emphasis area, as well as availability of funds.

VII. COST SHARING

Grantees will be expected to cost share a minimum of five percent.

VIII. FOR FURTHER INFORMATION CONTACT:

Mr. Ralph Touch
Acting Chief, Grants Administration
and Review Branch
National Institute for Occupational
Safety and Health
Centers for Disease Control
1600 Clifton Road, N.E.
Atlanta, Georgia 30333

Telephone: (404) 329-3773

or

Kenneth Bridbord, M.D.
Director, Office of Extramural Coordination
and Special Projects
National Institute for Occupational
Safety and Health
Westwood Building - Room 3A10
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-6723

(This program is described in the Catalog of Federal Domestic Assistance Program No. 13.262, Occupational Safety and Health Research Grants and is not subject to Health Systems Agency review.)

ANNOUNCEMENT

NURSING RESEARCH PROJECT GRANTS

NURSING RESEARCH PROGRAM GRANTS

NURSING RESEARCH EMPHASIS GRANTS FOR DOCTORAL PROGRAMS IN NURSING

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Application Receipt Dates: November 1, March 1, July 1

The Division of Nursing (DN), Bureau of Health Professions, Health Resources and Services Administration (HRSA), makes the following announcements regarding three components of its research support program authorized under Section 301 of the Public Health Service Act.

Section 301 authorizes the Secretary to award grants to any corporation, public or private institution or agency or other legal entity to enlarge the body of scientific knowledge that underlies nursing practice, nursing education, and nursing services administration; and to strengthen these areas through utilization of such knowledge.

These programs are listed at 13.361 in the Catalog of Federal Domestic Assistance, Nursing Research Project Grants. Applications submitted in response to this announcement are not subject to review by State and area-wide clearinghouses under the procedures in the Office of Management and Budget Circular No. A-95.

Application materials are being made available without final action on the related Fiscal Year 1984 budget.

I. NURSING RESEARCH PROJECT GRANTS

Applications for Nursing Research Project Grants, which are the traditional, discrete research projects performed by the named investigator(s) in an area representing her/his specific interest and competency, will continue to be accepted. Application deadline dates are November 1, March 1, and July 1.

II. NURSING RESEARCH PROGRAM GRANTS

The ceiling of $100,000 direct costs per year, which is currently a condition of application for an award of Nursing Research Program Grants is now eliminated. Instead, direct costs should be based solely on the fiscal needs of the component projects and any core requirements. Direct costs per year may, therefore, be either more or less than $100,000. This policy is effective for all applications--both competing and noncompeting--submitted after the date of publication of this announcement. The application deadline dates are October 1, February 1, and June 1.

III. NURSING RESEARCH EMPHASIS GRANTS FOR DOCTORAL PROGRAMS IN NURSING

The specific purpose of this program is to stimulate the development of nursing research in areas that emphasize special health needs of the Nation and to enhance the research efforts and resources of faculty in schools of nursing which offer doctoral programs. Students should be enrolled in the nursing doctoral program at the time of submission of an application. Application deadline dates are November 1, March 1, and July 1.

IV. APPLICATION PROCEDURES

Research grant application kits, PHS 398 (Rev. 5/82), are available through the research offices of most institutions. Applications may be submitted at any time to the following:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

Applications must be received by the above dates for consideration in the next review cycle. A package carrying a legible proof-of-mailing date assigned by the carriers, and which is no later than one week prior to the receipt date, is also acceptable. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following work day.

For further information contact:

Nursing Research Support Section
Nursing Research and Analysis Branch
Division of Nursing
Bureau of Health Professions
Health Resources and Services Administration
Parklawn Building - Room 5C-09
5600 Fishers Lane
Rockville, Maryland 20782

Telephone: (301) 443-6315

Questions regarding grants policy should be directed to:

Grants Management Officer
Bureau of Health Professions
Health Resources and Services Administration
Parklawn Building - Room 8C-22
5600 Fishers Lane
Rockville, Maryland 20782

Telephone: (301) 443-6915

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